II

107TH CONGRESS
1ST SESSION

S. 889

To protect consumers in managed care plans and in other health coverage.

IN THE SENATE OF THE UNITED STATES

MAY 15, 2001

Mr. FRIST (for himself, Mr. BREAUX, and Mr. JEFFORDS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To protect consumers in managed care plans and in other health coverage.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Bipartisan Patients' Bill of Rights Act of 2001''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—PATIENTS' BILL OF RIGHTS

Subtitle A—Right to Advice and Care

Sec. 101. Access to emergency medical care.
Sec. 102. Offering of choice of coverage options.

Sec. 103. Patient access to obstetric and gynecological care.
Sec. 104. Access to pediatric care.
Sec. 105. Timely access to specialists.
Sec. 106. Continuity of care.
Sec. 107. Protection of patient-provider communications.
Sec. 108. Patient's right to prescription drugs.
Sec. 109. Coverage for individuals participating in approved clinical trials.
Sec. 110. Required coverage for minimum hospital stay for mastectomies and lymph node dissections for the treatment of breast cancer and coverage for secondary consultations.
Sec. 111. Prohibition of discrimination against providers based on licensure.
Sec. 112. Generally applicable provision.

Subtitle B—Right to Information About Plans and Providers

Sec. 121. Health plan information.
Sec. 122. Information about providers.
Sec. 123. Study on the effect of physician compensation methods.

Subtitle C—Right to Hold Health Plans Accountable

Sec. 131. Amendments to Employee Retirement Income Security Act of 1974.
Sec. 132. Enforcement.

Subtitle D—Remedies

Sec. 141. Availability of court remedies.
Sec. 142. Limitation on certain class action litigation.
Sec. 143. Authority to impose civil penalties for failure to provide a plan benefit not eligible for medical review.

Subtitle E—State Flexibility

Sec. 151. Preemption; State flexibility; construction.
Sec. 152. Coverage of limited scope dental plans.

Subtitle F—Miscellaneous Provisions

Sec. 161. Definitions.

TITLE II—AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT

Sec. 201. Application to certain health insurance coverage.
Sec. 202. Application to individual health insurance coverage.
Sec. 203. Limitation on authority of the Secretary of Health and Human services with respect to non-Federal governmental plans.
Sec. 204. Cooperation between Federal and State authorities.

TITLE III—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

Sec. 301. Application of patient protection standards to group health plans and group health insurance coverage under the Employee Retirement Income Security Act of 1974.
Sec. 302. Cooperation between Federal and State authorities.

TITLE IV—AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986

Sec. 401. Application to group health plans under the Internal Revenue Code of 1986.
Sec. 402. Conforming enforcement for women's health and cancer rights.

TITLE V—EFFECTIVE DATE; SEVERABILITY

Sec. 501. Effective date and related rules.
Sec. 502. Severability.

TITLE I—PATIENTS' BILL OF RIGHTS

Subtitle A—Right to Advice and Care

SEC. 101. ACCESS TO EMERGENCY MEDICAL CARE.

(a) COVERAGE OF EMERGENCY SERVICES.—If a group health plan, and a health insurance issuer that offers health insurance coverage, provides coverage for any benefits consisting of emergency medical care, except for items or services specifically excluded from coverage, the plan or issuer shall, without regard to prior authorization or provider participation—

(1) provide coverage for emergency medical screening examinations to the extent that a prudent layperson, who possesses an average knowledge of health and medicine, would determine such examinations to be necessary; and

(2) provide coverage for additional emergency medical care to stabilize an emergency medical condition following an emergency medical screening examination (if determined necessary), pursuant to the

definition of stabilize under section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(b) COVERAGE OF EMERGENCY AMBULANCE SERVICES.—If a group health plan, and a health insurance issuer that offers health insurance coverage, provides coverage for any benefits consisting of emergency ambulance services, except for items or services specifically excluded from coverage, the plan or issuer shall, without regard to prior authorization or provider participation, provide coverage for emergency ambulance services to the extent that a prudent layperson, who possesses an average knowledge of health and medicine, would determine such emergency ambulance services to be necessary.

(c) CARE AFTER STABILIZATION.—

(1) IN GENERAL.—In the case of medically necessary and appropriate items or services related to the emergency medical condition that may be provided to a participant, beneficiary, or enrollee by a nonparticipating provider after the participant, beneficiary, or enrollee is stabilized, the nonparticipating provider shall contact the plan or issuer as soon as practicable, but not later than 1 hour after stabilization occurs, with respect to whether—

(A) the provision of items or services is approved;

(B) the participant, beneficiary, or enrollee will be transferred; or

(C) other arrangements will be made concerning the care and treatment of the participant, beneficiary, or enrollee.

(2) FAILURE TO RESPOND AND MAKE ARRANGEMENTS.—If a group health plan, and a health insurance issuer that offers health insurance coverage, fails to respond and make arrangements within 1 hour of being contacted in accordance with paragraph (1), then the plan or issuer shall be responsible for the cost of any additional items or services provided by the nonparticipating provider if—

(A) coverage for items or services of the type furnished by the nonparticipating provider is available under the plan or coverage;

(B) the items or services are medically necessary and appropriate and related to the emergency medical condition involved; and

(C) the timely provision of the items or services is medically necessary and appropriate.

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to apply to a group health plan, and a health insurance issuer that of-

fers health insurance coverage, that does not require prior authorization for items or services provided to a participant, beneficiary, or enrollee after the participant, beneficiary, or enrollee is stabilized.

(d) REIMBURSEMENT TO A NONPARTICIPATING PROVIDER.—The responsibility of a group health plan, and a health insurance issuer that offers health insurance coverage, to provide reimbursement to a nonparticipating provider under this section shall cease accruing upon the earlier of—

(1) the transfer or discharge of the participant, beneficiary, or enrollee; or

(2) the completion of other arrangements made by the plan or issuer and the nonparticipating provider.

(e) RESPONSIBILITY OF PARTICIPANT.—The coverage required under subsections (a), (b), and (c) shall be provided by a group health plan, and a health insurance issuer that offers health insurance coverage, in a manner so that, if the services referred to in such subsections are provided to a participant, beneficiary, or enrollee by a nonparticipating provider with or without prior authorization, the participant, beneficiary, or enrollee is not liable for amounts that exceed the amounts of liability that would

be incurred if the services were provided by a participating health care provider with prior authorization.

(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a group health plan or health insurance issuer from negotiating reimbursement rates with a nonparticipating provider for items or services provided under this section.

(g) DEFINITIONS.—In this section:

(1) EMERGENCY AMBULANCE SERVICES.—The term ''emergency ambulance services'' means, with respect to a participant, beneficiary, or enrollee under a group health plan, or a health insurance issuer that offers health insurance coverage, ambulance services furnished to transport an individual who has an emergency medical condition to a treating facility for receipt of emergency medical care if—

(A) the emergency services are covered under the group health plan or health insurance coverage involved; and

(B) a prudent layperson who possesses an average knowledge of health and medicine could reasonably expect the absence of such emergency transport to result in placing the health of the participant, beneficiary, or enrollee (or,

with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.

(2) EMERGENCY MEDICAL CARE.—The term ''emergency medical care'' means, with respect to a participant, beneficiary, or enrollee under a group health plan, or a health insurance issuer that offers health insurance coverage, covered inpatient and outpatient items or services that—

(A) are furnished by any provider, including a nonparticipating provider, that is qualified to furnish such items or services; and

(B) are needed to evaluate or stabilize (as such term is defined in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)) an emergency medical condition.

(3) EMERGENCY MEDICAL CONDITION.—The term ''emergency medical condition'' means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to

result in placing the health of the participant, beneficiary, or enrollee (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.

SEC. 102. OFFERING OF CHOICE OF COVERAGE OPTIONS.

(a) REQUIREMENT.—If a group health plan provides coverage for benefits only through a defined set of participating health care professionals, the plan shall offer the participant the option to purchase point-of-service coverage (as defined in subsection (b)) for all such benefits for which coverage is otherwise so limited. Such option shall be made available to the participant at the time of enrollment under the plan and at such other times as the plan offers the participant a choice of coverage options.

(b) POINT-OF-SERVICE COVERAGE DEFINED.—In this section, the term ''point-of-service coverage'' means, with respect to benefits covered under a group health plan coverage of such benefits when provided by a nonparticipating health care professional.

(c) SMALL EMPLOYER EXEMPTION.—

(1) IN GENERAL.—This section shall not apply to any group health plan with respect to a small employer.

(2) SMALL EMPLOYER.—For purposes of paragraph (1), the term ''small employer'' means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 2 but not more than 25 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year. For purposes of this paragraph, the provisions of subparagraph (C) of section 712(c)(1) shall apply in determining employer size.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) as requiring coverage for benefits for a particular type of health care professional;

(2) as preventing a group health plan from imposing higher premiums or cost-sharing on a participant for the exercise of a point-of-service coverage option; or

(3) to require that a group health plan include coverage of health care professionals that the plan excludes because of fraud, quality of care, or other similar reasons with respect to such professionals.

(e) SPECIAL POINT OF SERVICE PROTECTION FOR INDIVIDUALS IN DENTAL PLANS.—For purposes of apply-

ing the requirements of this section under sections 2707 and 2753 of the Public Health Service Act and section 714 of the Employee Retirement Income Security Act of 1974, section 2791(c)(2)(A) of the Public Health Service Act and section 733(c)(2)(A) of the Employee Retirement Income Security Act of 1974, only relating to limited scope dental benefits, shall be deemed not to apply.

SEC. 103. PATIENT ACCESS TO OBSTETRIC AND GYNECOLOGICAL CARE.

(a) GENERAL RIGHTS.—

(1) DIRECT ACCESS.—A group health plan, and a health insurance issuer that offers health insurance coverage, described in subsection (b) may not require authorization or referral by the primary care provider described in subsection (b)(2) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating physician who specializes in obstetrics or gynecology.

(2) OBSTETRICAL AND GYNECOLOGICAL CARE.—A group health plan, and a health insurance issuer that offers health insurance coverage, described in subsection (b) shall treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and

services, pursuant to the direct access described under paragraph (1), by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(b) APPLICATION OF SECTION.—A group health plan, and a health insurance issuer that offers health insurance coverage, described in this subsection is a plan or issuer, that—

(1) provides coverage for obstetric or gynecologic care; and

(2) requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider other than a physician who specializes in obstetrics or gynecology.

(c) RULES OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) to require that a group health plan or a health insurance issuer approve or provide coverage for—

(A) any items or services that are not covered under the terms and conditions of the plan or coverage;

(B) any items or services that are not medically necessary and appropriate; or

(C) any items or services that are provided, ordered, or otherwise authorized under subsection (a)(2) by a physician unless such items or services are related to obstetric or gynecologic care;

(2) to preclude a group health plan or health insurance issuer from requiring that the physician described in subsection (a) notify the designated primary care professional or case manager of treatment decisions in accordance with a process implemented by the plan or issuer, except that the plan or issuer shall not impose such a notification requirement on the participant, beneficiary, or enrollee involved in the treatment decision;

(3) to preclude a group health plan or health insurance issuer from requiring authorization, including prior authorization, for certain items and services from the physician described in subsection (a) who specializes in obstetrics and gynecology if the designated primary care provider of the participant, beneficiary, or enrollee would otherwise be required to obtain authorization for such items or services;

(4) to require that the participant, beneficiary, or enrollee described in subsection (a)(1) obtain au-

thorization or a referral from a primary care provider in order to obtain obstetrical or gynecological care from a health care professional other than a physician if the provision of obstetrical or gynecological care by such professional is permitted by the group health plan or health insurance coverage and consistent with State licensure, credentialing, and scope of practice laws and regulations; or

(5) to preclude the participant, beneficiary, or enrollee described in subsection (a)(1) from designating a health care professional other than a physician as a primary care provider if such designation is permitted by the group health plan or health insurance issuer and the treatment by such professional is consistent with State licensure, credentialing, and scope of practice laws and regulations.

SEC. 104. ACCESS TO PEDIATRIC CARE.

(a) PEDIATRIC CARE.—If a group health plan, and a health insurance issuer that offers health insurance coverage, requires or provides for a participant, beneficiary, or enrollee to designate a participating primary care provider for a child of such participant, beneficiary, or enrollee, the plan or issuer shall permit the participant, beneficiary, or enrollee to designate a physician who special-

izes in pediatrics as the child's primary care provider if such provider participates in the network of the plan or issuer.

(b) RULES OF CONSTRUCTION.—With respect to the child of a participant, beneficiary, or enrollee, nothing in subsection (a) shall be construed to—

(1) require that the participant, beneficiary, or enrollee obtain prior authorization or a referral from a primary care provider in order to obtain pediatric care from a health care professional other than a physician if the provision of pediatric care by such professional is permitted by the plan or issuer and consistent with State licensure, credentialing, and scope of practice laws and regulations; or

(2) preclude the participant, beneficiary, or enrollee from designating a health care professional other than a physician as a primary care provider for the child if such designation is permitted by the plan or issuer and the treatment by such professional is consistent with State licensure, credentialing, and scope of practice laws.

SEC. 105. TIMELY ACCESS TO SPECIALISTS.

(a) TIMELY ACCESS.—

(1) REQUIREMENT OF COVERAGE.—

(A) IN GENERAL.—A group health plan, and a health insurance issuer that offers health insurance coverage, shall ensure that participants, beneficiaries, and enrollees receive timely coverage for access to appropriate medical specialists when such specialty care is a covered benefit under the plan or coverage.

(B) APPROPRIATE MEDICAL SPECIALIST DEFINED.—In this subsection, the term ''appropriate medical specialist'' means a physician (including an alleopathic or osteopathic physician) or health care professional who is appropriately credentialed or licensed in 1 or more States and who typically treats the diagnosis or condition of the participant, beneficiary, or enrollee.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

(A) to require the coverage under a group health plan, or health insurance coverage, of benefits or services;

(B) to prohibit a plan or health insurance issuer from including providers in the network only to the extent necessary to meet the needs

of the plan's or issuer's participants, beneficiaries, or enrollees;

(C) to prohibit a plan or issuer from establishing measures designed to maintain quality and control costs consistent with the responsibilities of the plan or issuer; or

(D) to override any State licensure or scope-of-practice law.

(3) ACCESS TO CERTAIN PROVIDERS.—

(A) PARTICIPATING PROVIDERS.—Nothing in this section shall be construed to prohibit a group health plan, or a health insurance issuer that offers health insurance coverage, from requiring that a participant, beneficiary, or enrollee obtain specialty care from a participating specialist.

(B) NONPARTICIPATING PROVIDERS.—

(i) IN GENERAL.—With respect to specialty care under this section, if a group health plan, or a health insurance issuer that offers health insurance coverage, determines that a participating specialist is not available to provide such care to the participant, beneficiary, or enrollee, the

plan or issuer shall provide for coverage of such care by a nonparticipating specialist.

(ii) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a group health plan, or a health insurance issuer that offers health insurance coverage, refers a participant, beneficiary, or enrollee to a nonparticipating specialist pursuant to clause (i), such specialty care shall be provided at no additional cost to the participant, beneficiary, or enrollee beyond what the participant, beneficiary, or enrollee would otherwise pay for such specialty care if provided by a participating specialist.

(b) REFERRALS.—

(1) AUTHORIZATION.—Nothing in this section shall be construed to prohibit a group health plan, or a health insurance issuer that offers health insurance coverage, from requiring an authorization in order to obtain coverage for specialty services so long as such authorization is for an appropriate duration or number of referrals.

(2) REFERRALS FOR ONGOING SPECIAL CONDITIONS.—

(A) IN GENERAL.—A group health plan, and a health insurance issuer that offers health insurance coverage, shall permit a participant, beneficiary, or enrollee who has an ongoing special condition (as defined in subparagraph (B)) to receive a referral to a specialist for the treatment of such condition and such specialist may authorize such referrals, procedures, tests, and other medical services with respect to such condition, or coordinate the care for such condition, subject to the terms of a treatment plan referred to in subsection (c) with respect to the condition.

(B) ONGOING SPECIAL CONDITION DEFINED.—In this subsection, the term ''ongoing special condition'' means a condition or disease that—

(i) is life-threatening, degenerative, or disabling; and

(ii) requires specialized medical care over a prolonged period of time.

(c) TREATMENT PLANS.—

(1) IN GENERAL.—Nothing in this section shall be construed to prohibit a group health plan, or a health insurance issuer that offers health insurance

coverage, from requiring that specialty care be provided pursuant to a treatment plan so long as the treatment plan is—

(A) developed by the specialist, in consultation with the case manager or primary care provider, and the participant, beneficiary, or enrollee; and

(B) if the plan or issuer requires such approval, approved in a timely manner by the plan or issuer consistent with the applicable quality assurance and utilization review standards of the plan or issuer.

(2) NOTIFICATION.—Nothing in paragraph (1) shall be construed as prohibiting a plan or issuer from requiring the specialist to provide the plan or issuer with regular updates on the specialty care provided, as well as all other necessary medical information.

(d) SPECIALIST DEFINED.—For purposes of this section, the term ''specialist'' means, with respect to the medical condition of the participant, beneficiary, or enrollee, a health care professional, facility, or center (such as a center of excellence) that has adequate expertise (including age-appropriate expertise) through appropriate training and experience.

SEC. 106. CONTINUITY OF CARE.

(a) TERMINATION OF PROVIDER.—If a contract between a group health plan, and a health insurance issuer that offers health insurance coverage, and a treating health care provider is terminated (as defined in paragraph (e)(4)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in such plan or coverage, and an individual who is a participant, beneficiary or enrollee under such plan or coverage is undergoing an active course of treatment for a serious and complex condition, institutional care, pregnancy, or terminal illness from the provider at the time the plan or issuer receives or provides notice of such termination, the plan or issuer shall—

(1) notify the individual, or arrange to have the individual notified pursuant to subsection (d)(2), on a timely basis of such termination;

(2) provide the individual with an opportunity to notify the plan or issuer of the individual's need for transitional care; and

(3) subject to subsection (c), permit the individual to elect to continue to be covered with respect to the active course of treatment with the provider's consent during a transitional period (as provided for under subsection (b)).

(b) TRANSITIONAL PERIOD.—

(1) SERIOUS AND COMPLEX CONDITIONS.—The transitional period under this section with respect to a serious and complex condition shall extend for up to 90 days from the date of the notice described in subsection (a)(1) of the provider's termination.

(2) INSTITUTIONAL OR INPATIENT CARE.—

(A) IN GENERAL.—The transitional period under this section for institutional or non-elective inpatient care from a provider shall extend until the earlier of—

(i) the expiration of the 90-day period beginning on the date on which the notice described in subsection (a)(1) of the provider's termination is provided; or

(ii) the date of discharge of the individual from such care or the termination of the period of institutionalization.

(B) SCHEDULED CARE.—The 90 day limitation described in subparagraph (A)(i) shall include post-surgical follow-up care relating to non-elective surgery that has been scheduled before the date of the notice of the termination of the provider under subsection (a)(1).

(3) PREGNANCY.—If—

(A) a participant, beneficiary, or enrollee has entered the second trimester of pregnancy at the time of a provider's termination of participation; and

(B) the provider was treating the pregnancy before the date of the termination;

the transitional period under this subsection with respect to provider's treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

(4) TERMINAL ILLNESS.—If—

(A) a participant, beneficiary, or enrollee was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) at the time of a provider's termination of participation; and

(B) the provider was treating the terminal illness before the date of termination;

the transitional period under this subsection shall extend for the remainder of the individual's life for care that is directly related to the treatment of the terminal illness.

(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan, and a health insurance issuer that offers health insurance coverage, may condition coverage of

continued treatment by a provider under this section upon the provider agreeing to the following terms and conditions:

(1) The treating health care provider agrees to accept reimbursement from the plan or issuer and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or at the rates applicable under the replacement plan after the date of the termination of the contract with the plan or issuer) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in this section had not been terminated.

(2) The treating health care provider agrees to adhere to the quality assurance standards of the plan or issuer responsible for payment under paragraph (1) and to provide to such plan or issuer necessary medical information related to the care provided.

(3) The treating health care provider agrees otherwise to adhere to such plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and pro-

viding services pursuant to a treatment plan (if any) approved by the plan or issuer.

(d) RULES OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider; or

(2) with respect to the termination of a contract under subsection (a) to prevent a group health plan or health insurance issuer from requiring that the health care provider—

(A) notify participants, beneficiaries, or enrollees of their rights under this section; or

(B) provide the plan or issuer with the name of each participant, beneficiary, or enrollee who the provider believes is eligible for transitional care under this section.

(e) DEFINITIONS.—In this section:

(1) CONTRACT.—The term ''contract between a group health plan, and a health insurance issuer that offers health insurance coverage, and a treating health care provider'' shall include a contract between such a plan or issuer and an organized network of providers.

(2) HEALTH CARE PROVIDER.—The term ''health care provider'' or ''provider'' means—

(A) any individual who is engaged in the delivery of health care services in a State and who is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State; and

(B) any entity that is engaged in the delivery of health care services in a State and that, if it is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State, is so licensed.

(3) SERIOUS AND COMPLEX CONDITION.—The term ''serious and complex condition'' means, with respect to a participant, beneficiary, or enrollee under the plan or coverage, a condition that is medically determinable and—

(A) in the case of an acute illness, is a condition serious enough to require specialized medical treatment to avoid the reasonable possibility of death or permanent harm; or

(B) in the case of a chronic illness or condition, is an illness or condition that—

(i) is complex and difficult to manage;

(ii) is disabling or life- threatening; and

(iii) requires—

(I) frequent monitoring over a prolonged period of time and requires substantial on-going specialized medical care; or

(II) frequent ongoing specialized medical care across a variety of domains of care.

(4) TERMINATED.—The term ''terminated'' includes, with respect to a contract (as defined in paragraph (1)), the expiration or nonrenewal of the contract by the group health plan or health insurance issuer, but does not include a termination of the contract by the plan or issuer for failure to meet applicable quality standards or for fraud.

SEC. 107. PROTECTION OF PATIENT-PROVIDER COMMUNICATIONS.

(a) IN GENERAL.—Subject to subsection (b), a group health plan, and a health insurance issuer that offers health insurance coverage, (in relation to a participant, beneficiary, or enrollee) shall not prohibit or otherwise restrict a health care professional from advising such a participant, beneficiary, or enrollee who is a patient of the

professional about the health status of the participant, beneficiary, or enrollee or medical care or treatment for the condition or disease of the participant, beneficiary, or enrollee, regardless of whether coverage for such care or treatment are provided under the contract, if the professional is acting within the lawful scope of practice.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as requiring a group health plan, or a health insurance issuer that offers health insurance coverage, to provide specific benefits under the terms of such plan or coverage.

SEC. 108. PATIENT'S RIGHT TO PRESCRIPTION DRUGS.

(a) IN GENERAL.—To the extent that a group health plan, and a health insurance issuer that offers health insurance coverage, provides coverage for benefits with respect to prescription drugs, and limits such coverage to drugs included in a formulary, the plan or issuer shall—

(1) ensure the participation of physicians and pharmacists in developing and reviewing such formulary; and

(2) in accordance with the applicable quality assurance and utilization review standards of the plan or issuer, provide for exceptions from the formulary limitation when a non-formulary alternative is medically necessary and appropriate.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a group health plan, or a health insurance issuer that offers health insurance coverage, from excluding coverage for a specific drug or class of drugs if such drugs or class of drugs is expressly excluded under the terms and conditions of the plan or coverage.

SEC. 109. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

(a) COVERAGE.—

(1) IN GENERAL.—If a group health plan, and a health insurance issuer that offers health insurance coverage, provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

(B) subject to subsections (b), (c), and (d) may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

(C) may not discriminate against the individual on the basis of the participant's, beneficiaries, or enrollee's participation in such trial.

(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term ''qualified individual'' means an individual who is a participant or beneficiary in a group health plan or an enrollee in health insurance coverage and who meets the following conditions:

(1)(A) The individual has a life-threatening or serious illness for which no standard treatment is effective.

(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

(C) The individual's participation in the trial offers meaningful potential for significant clinical benefit for the individual.

(2) Either—

(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

(B) the participant, beneficiary, or enrollee provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

(c) PAYMENT.—

(1) IN GENERAL.—Under this section a group health plan, and a health insurance issuer that offers health insurance coverage, shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of

items and services that are reasonably expected to be paid for by the sponsors of an approved clinical trial.

(2) STANDARDS FOR DETERMINING ROUTINE PATIENT COSTS ASSOCIATED WITH CLINICAL TRIAL PARTICIPATION.—

(A) IN GENERAL.—The Secretary shall, in accordance with this paragraph, establish standards relating to the coverage of routine patient costs for individuals participating in clinical trials that group health plans and health insurance issuers must meet under this section.

(B) FACTORS.—In establishing routine patient cost standards under subparagraph (A), the Secretary shall consult with interested parties and take into account —

(i) quality of patient care;

(ii) routine patient care costs versus costs associated with the conduct of clinical trials, including unanticipated patient care costs as a result of participation in clinical trials; and

(iii) previous and on-going studies relating to patient care costs associated with participation in clinical trials.

(C) APPOINTMENT AND MEETINGS OF NEGOTIATED RULEMAKING COMMITTEE.—

(i) PUBLICATION OF NOTICE.—Not later than November 15, 2002, the Secretary shall publish notice of the establishment of a negotiated rulemaking committee, as provided for under section 564(a) of title 5, United States Code, to develop the standards described in subparagraph (A), which shall include—

(I) the proposed scope of the committee;

(II) the interests that may be impacted by the standards;

(III) a list of the proposed membership of the committee;

(IV) the proposed meeting schedule of the committee;

(V) a solicitation for public comment on the committee; and

(VI) the procedures under which an individual may apply for membership on the committee.

(ii) COMMENT PERIOD.—Notwithstanding section 564(c) of title 5, United

States Code, the Secretary shall provide for a period, beginning on the date on which the notice is published under clause (i) and ending on November 30, 2002, for the submission of public comments on the committee under this subparagraph.

(iii) APPOINTMENT OF COMMITTEE.—Not later than December 30, 2001, the Secretary shall appoint the members of the negotiated rulemaking committee under this subparagraph.

(iv) FACILITATOR.—Not later than January 10, 2003, the negotiated rulemaking committee shall nominate a facilitator under section 566(c) of title 5, United States Code, to carry out the activities described in subsection (d) of such section.

(v) MEETINGS.—During the period beginning on the date on which the facilitator is nominated under clause (iv) and ending on March 30, 2003, the negotiated rulemaking committee shall meet to develop the standards described in subparagraph (A).

(D) PRELIMINARY COMMITTEE REPORT.—

(i) IN GENERAL.—The negotiated rulemaking committee appointed under subparagraph (C) shall report to the Secretary, by not later than March 30, 2003, regarding the committee's progress on achieving a consensus with regard to the rulemaking proceedings and whether such consensus is likely to occur before the target date described in subsection (F).

(ii) TERMINATION OF PROCESS AND PUBLICATION OF RULE BY SECRETARY.—If the committee reports under clause (i) that the committee has failed to make significant progress towards such consensus or is unlikely to reach such consensus by the target date described in subsection (F), the Secretary shall terminate such process and provide for the publication in the Federal Register, by not later than June 30, 2003, of a rule under this paragraph through such other methods as the Secretary may provide.

(E) FINAL COMMITTEE REPORT AND PUBLICATION OF RULE BY SECRETARY.—

(i) IN GENERAL.—If the rulemaking committee is not terminated under subparagraph (D)(ii), the committee shall submit to the Secretary, by not later than May 30, 2003, a report containing a proposed rule.

(ii) PUBLICATION OF RULE.—If the Secretary receives a report under clause (i), the Secretary shall provide for the publication in the Federal Register, by not later than June 30, 2003, of the proposed rule.

(F) TARGET DATE FOR PUBLICATION OF RULE.—As part of the notice under subparagraph (C)(i), and for purposes of this paragraph, the ''target date for publication'' (referred to in section 564(a)(5) of title 5, United States Code) shall be June 30, 2003.

(G) EFFECTIVE DATE.—The provisions of this paragraph shall apply to group health plans and health insurance issuers that offer health insurance coverage for plan or coverage years beginning on or after January 1, 2004.

(3) PAYMENT RATE.—In the case of covered items and services provided by—

(A) a participating provider, the payment rate shall be at the agreed upon rate, or

(B) a nonparticipating provider, the payment rate shall be at the rate the plan or issuer would normally pay for comparable services under subparagraph (A).

(d) APPROVED CLINICAL TRIAL DEFINED.—

(1) IN GENERAL.—In this section, the term ''approved clinical trial'' means a clinical research study or clinical investigation approved or funded (which may include funding through in-kind contributions) by one or more of the following:

(A) The National Institutes of Health.

(B) A cooperative group or center of the National Institutes of Health.

(C) Either of the following if the conditions described in paragraph (2) are met:

(i) The Department of Veterans Affairs.

(ii) The Department of Defense.

(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed

and approved through a system of peer review that the Secretary determines—

(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

(e) CONSTRUCTION.—Nothing in this section shall be construed to preclude a plan or issuer from offering coverage that is broader than the coverage required under this section with respect to clinical trials.

(f) PLAN SATISFACTION OF CERTAIN REQUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

(1) IN GENERAL.—For purposes of this section, insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the requirements of this section with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer.

(2) CONSTRUCTION.—Nothing in this section shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B.

(g) STUDY AND REPORT.—

(1) STUDY.—The Secretary shall study the impact on group health plans and health insurance issuers for covering routine patient care costs for individuals who are entitled to benefits under this section and who are enrolled in an approved clinical trial program.

(2) REPORT TO CONGRESS.—Not later than January 1, 2006, the Secretary shall submit a report to Congress that contains an assessment of—

(A) any incremental cost to group health plans and health insurance issuers resulting from the provisions of this section;

(B) a projection of expenditures to such plans and issuers resulting from this section; and

(C) any impact on premiums resulting from this section.

SEC. 110. REQUIRED COVERAGE FOR MINIMUM HOSPITAL STAY FOR MASTECTOMIES AND LYMPH NODE DISSECTIONS FOR THE TREATMENT OF BREAST CANCER AND COVERAGE FOR SECONDARY CONSULTATIONS.

(a) INPATIENT CARE.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer that offers health insurance coverage, that provides medical and surgical benefits shall ensure that inpatient coverage with respect to the treatment of breast cancer is provided for a period of time as is determined by the attending physician, in consultation with the patient, to be medically necessary and appropriate following—

(A) a mastectomy;

(B) a lumpectomy; or

(C) a lymph node dissection for the treatment of breast cancer.

(2) EXCEPTION.—Nothing in this section shall be construed as requiring the provision of inpatient coverage if the attending physician and patient determine that a shorter period of hospital stay is medically appropriate.

(b) PROHIBITION ON CERTAIN MODIFICATIONS.—In implementing the requirements of this section, a group health plan, and a health insurance issuer that offers

health insurance coverage, may not modify the terms and conditions of coverage based on the determination by a participant, beneficiary, or enrollee to request less than the minimum coverage required under subsection (a).

(c) SECONDARY CONSULTATIONS.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer that offers health insurance coverage, that provides coverage with respect to medical and surgical services provided in relation to the diagnosis and treatment of cancer shall ensure that full coverage is provided for secondary consultations by specialists in the appropriate medical fields (including pathology, radiology, and oncology) to confirm or refute such diagnosis. Such plan or issuer shall ensure that full coverage is provided for such secondary consultation whether such consultation is based on a positive or negative initial diagnosis. In any case in which the attending physician certifies in writing that services necessary for such a secondary consultation are not sufficiently available from specialists operating under the plan or coverage with respect to whose services coverage is otherwise provided under such plan or by such issuer, such plan or issuer shall ensure that coverage is provided with respect to the services necessary for the secondary

consultation with any other specialist selected by the attending physician for such purpose at no additional cost to the individual beyond that which the individual would have paid if the specialist was participating in the network of the plan or issuer.

(2) EXCEPTION.—Nothing in paragraph (1) shall be construed as requiring the provision of secondary consultations where the patient determines not to seek such a consultation.

(d) PROHIBITION ON PENALTIES OR INCENTIVES.—A group health plan, and a health insurance issuer that offers health insurance coverage, may not—

(1) penalize or otherwise reduce or limit the reimbursement of a provider or specialist because the provider or specialist provided care to a participant, beneficiary, or enrollee in accordance with this section;

(2) provide financial or other incentives to a physician or specialist to induce the physician or specialist to keep the length of inpatient stays of patients following a mastectomy, lumpectomy, or a lymph node dissection for the treatment of breast cancer below certain limits or to limit referrals for secondary consultations; or

(3) provide financial or other incentives to a physician or specialist to induce the physician or specialist to refrain from referring a participant, beneficiary, or enrollee for a secondary consultation that would otherwise be covered by the plan or coverage involved under subsection (c).

SEC. 111. PROHIBITION OF DISCRIMINATION AGAINST PROVIDERS BASED ON LICENSURE.

(a) IN GENERAL.—A group health plan, and a health insurance issuer that offers health insurance coverage, shall not discriminate with respect to participation or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification.

(b) CONSTRUCTION.—Subsection (a) shall not be construed—

(1) as requiring the coverage under a group health plan or health insurance coverage, of a particular benefit or service or to prohibit a plan or issuer from including providers only to the extent necessary to meet the needs of the plan's or issuer's participants, beneficiaries, or enrollees or from establishing any measure designed to maintain quality

and control costs consistent with the responsibilities of the plan or issuer;

(2) to override any State licensure or scope-of-practice law; or

(3) as requiring a plan or issuer that offers network coverage to include for participation every willing provider who meets the terms and conditions of the plan or coverage.

SEC. 112. GENERALLY APPLICABLE PROVISION.

Notwithstanding section 102, in the case of a group health plan, and a health insurance issuer that offers health insurance coverage, that provides benefits under 2 or more coverage options, the requirements of this subpart shall apply separately with respect to each coverage option.

Subtitle B—Right to Information About Plans and Providers

SEC. 121. HEALTH PLAN INFORMATION.

(a) REQUIREMENT.—

(1) DISCLOSURE.—

(A) IN GENERAL.—A group health plan, and a health insurance issuer that offers health insurance coverage, shall provide for the disclosure of the information described in subsection

(b) to participants, beneficiaries, and enrollees—

(i) at the time of the initial enrollment of the participant, beneficiary, or enrollee under the plan or coverage;

(ii) on an annual basis after enrollment—

(I) in conjunction with the election period of the plan or coverage if the plan or coverage has such an election period; or

(II) in the case of a plan or coverage that does not have an election period, in conjunction with the beginning of the plan or coverage year; and

(iii) in the case of any material reduction to the benefits or information described in paragraphs (1), (2) and (3) of subsection (b), in the form of a summary notice provided not later than the date on which the reduction takes effect.

(B) PARTICIPANTS, BENEFICIARIES, OR ENROLLEES.—The disclosure required under subparagraph (A) shall be provided—

(i)(I) jointly to each participant and beneficiary who reside at the same address; or

(II) in the case of a beneficiary who does not reside at the same address as the participant, separately to the participant and such beneficiary; and

(ii) to each enrollee.

(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prevent a group health plan sponsor and health insurance issuer from entering into an agreement under which either the plan sponsor or the issuer agrees to assume responsibility for compliance with the requirements of this section, in whole or in part, and the party delegating such responsibility is released from liability for compliance with the requirements that are assumed by the other party, to the extent the party delegating such responsibility did not cause such noncompliance.

(3) PROVISION OF INFORMATION.—Information shall be provided to participants, beneficiaries, and enrollees under this section at the last known address maintained by the plan or issuer with respect to such participants, beneficiaries, or enrollees, to the extent that such information is provided to par-

ticipants, beneficiaries, or enrollees via the United States Postal Service or other private delivery service.

(b) REQUIRED INFORMATION.—The informational materials to be distributed under this section shall include for each option available under the group health plan or health insurance coverage the following:

(1) BENEFITS.—A description of the covered benefits, including—

(A) any in- and out-of-network benefits;

(B) specific preventative services covered under the plan or coverage if such services are covered;

(C) any benefit limitations, including any annual or lifetime benefit limits and any monetary limits or limits on the number of visits, days, or services, and any specific coverage exclusions; and

(D) any definition of medical necessity used in making coverage determinations by the plan, issuer, or claims administrator.

(2) COST SHARING.—A description of any cost-sharing requirements, including—

(A) any premiums, deductibles, coinsurance, copayment amounts, and liability for bal-

ance billing above any reasonable and customary charges, for which the participant, beneficiary, or enrollee will be responsible under each option available under the plan;

(B) any maximum out-of-pocket expense for which the participant, beneficiary, or enrollee may be liable;

(C) any cost-sharing requirements for out-of-network benefits or services received from nonparticipating providers; and

(D) any additional cost-sharing or charges for benefits and services that are furnished without meeting applicable plan or coverage requirements, such as prior authorization or precertification.

(3) SERVICE AREA.—A description of the plan or issuer's service area, including the provision of any out-of-area coverage.

(4) PARTICIPATING PROVIDERS.—A directory of participating providers (to the extent a plan or issuer provides coverage through a network of providers) that includes, at a minimum, the name, address, and telephone number of each participating provider, and information about how to inquire

whether a participating provider is currently accepting new patients.

(5) CHOICE OF PRIMARY CARE PROVIDER.—A description of any requirements and procedures to be used by participants, beneficiaries, and enrollees in selecting, accessing, or changing their primary care provider, including providers both within and outside of the network (if the plan or issuer permits out-of-network services), and the right to select a pediatrician as a primary care provider under section 104 for a participant, beneficiary, or enrollee who is a child if such section applies.

(6) PREAUTHORIZATION REQUIREMENTS.—A description of the requirements and procedures to be used to obtain preauthorization for health services, if such preauthorization is required.

(7) EXPERIMENTAL AND INVESTIGATIONAL TREATMENTS.—A description of the process for determining whether a particular item, service, or treatment is considered experimental or investigational, and the circumstances under which such treatments are covered by the plan or issuer.

(8) SPECIALTY CARE.—A description of the requirements and procedures to be used by participants, beneficiaries, and enrollees in accessing spe-

cialty care and obtaining referrals to participating and nonparticipating specialists, including the right to timely coverage for access to specialists care under section 105 if such section applies.

(9) CLINICAL TRIALS.—A description the circumstances and conditions under which participation in clinical trials is covered under the terms and conditions of the plan or coverage, and the right to obtain coverage for approved cancer clinical trials under section 109 if such section applies.

(10) PRESCRIPTION DRUGS.—To the extent the plan or issuer provides coverage for prescription drugs, a statement of whether such coverage is limited to drugs included in a formulary, a description of any provisions and cost-sharing required for obtaining on- and off-formulary medications, and a description of the rights of participants, beneficiaries, and enrollees in obtaining access to access to prescription drugs under section 107 if such section applies.

(11) EMERGENCY SERVICES.—A summary of the rules and procedures for accessing emergency services, including the right of a participant, beneficiary, or enrollee to obtain emergency services under the prudent layperson standard under section

101, if such section applies, and any educational information that the plan or issuer may provide regarding the appropriate use of emergency services.

(12) CLAIMS AND APPEALS.—A description of the plan or issuer's rules and procedures pertaining to claims and appeals, a description of the rights of participants, beneficiaries, or enrollees under sections 503, 503A and 503B of the Employee Retirement Income Security Act of 1974 (or sections 2707(b) and 2753(b) of the Public Health Service with respect to non-Federal governmental plans and individual health insurance coverage) in obtaining covered benefits, filing a claim for benefits, and appealing coverage decisions internally and externally (including telephone numbers and mailing addresses of the appropriate authority), and a description of any additional legal rights and remedies available under section 502 of the Employee Retirement Income Security Act of 1974.

(13) ADVANCE DIRECTIVES AND ORGAN DONATION.—A description of procedures for advance directives and organ donation decisions if the plan or issuer maintains such procedures.

(14) INFORMATION ON PLANS AND ISSUERS.—The name, mailing address, and telephone number

or numbers of the plan administrator and the issuer to be used by participants, beneficiaries, and enrollees seeking information about plan or coverage benefits and services, payment of a claim, or authorization for services and treatment. The name of the designated decision-maker (or decision-makers) appointed under section 502(n)(2) of the Employee Retirement Income Security Act of 1974 for purposes of making final determinations under section 503A of such Act and approving coverage pursuant to the written determination of an independent medical reviewer under section 503B of such Act. Notice of whether the benefits under the plan are provided under a contract or policy of insurance issued by an issuer, or whether benefits are provided directly by the plan sponsor who bears the insurance risk.

(15) TRANSLATION SERVICES.—A summary description of any translation or interpretation services (including the availability of printed information in languages other than English, audio tapes, or information in Braille) that are available for non-English speakers and participants, beneficiaries, and enrollees with communication disabilities and a description of how to access these items or services.

(16) ACCREDITATION INFORMATION.—Any information that is made public by accrediting organizations in the process of accreditation if the plan or issuer is accredited, or any additional quality indicators (such as the results of enrollee satisfaction surveys) that the plan or issuer makes public or makes available to participants, beneficiaries, and enrollees.

(17) NOTICE OF REQUIREMENTS.—A description of any rights of participants, beneficiaries, and enrollees that are established by this Act (excluding those described in paragraphs (1) through (16)) if such rights apply. The description required under this paragraph may be combined with the notices required under sections 711(d), 713(b), or 606(a)(1) of the Employee Retirement Income Security Act of 1974, and with any other notice provision that the Secretary determines may be combined.

(18) COMPENSATION METHODS.—A summary description of the methods (including capitation, fee-for-service, salary, withholds, bonuses, bundled payments, per diem, or a combination thereof) used for compensating participating health care professionals (including primary care providers and specialists) and facilities in connection with the provision of health care under the plan or coverage. The require-

ment of this paragraph shall not be construed as requiring plans or issuers to provide information concerning proprietary payment methodology.

(19) AVAILABILITY OF ADDITIONAL INFORMATION.—A statement that the information described in subsection (c), and instructions on obtaining such information (including telephone numbers and, if available, Internet websites), shall be made available upon request.

(c) ADDITIONAL INFORMATION.—The informational materials to be provided upon the request of a participant, beneficiary, or enrollees shall include for each option available under a group health plan or health insurance coverage the following:

(1) STATUS OF PROVIDERS.—The State licensure status of the plan or issuer's participating health care professionals and participating health care facilities, and, if available, the education, training, specialty qualifications or certifications of such professionals.

(2) PRESCRIPTION DRUGS.—Information about whether a specific prescription medication is included in the formulary of the plan or issuer, if the plan or issuer uses a defined formulary.

(3) EXTERNAL APPEALS INFORMATION.—Aggregate information on the number and outcomes of external medical reviews, relative to the sample size (such as the number of covered lives) determined for the plan or issuer's book of business.

(d) MANNER OF DISCLOSURE.—The information described in this section shall be disclosed in an accessible medium and format that is calculated to be understood by the average participant.

(e) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a group health plan, or a health insurance issuer that offers health insurance coverage, from—

(1) distributing any other additional information determined by the plan or issuer to be important or necessary in assisting participants, beneficiaries, and enrollees in the selection of a health plan; and

(2) complying with the provisions of this section by providing information in brochures, through the Internet or other electronic media, or through other similar means, so long as participants, beneficiaries, and enrollees are provided with an opportunity to request that informational materials be provided in printed form.

(f) CONFORMING REGULATIONS.—The Secretary shall issue regulations to coordinate the requirements on group health plans and health insurance issuers under this section with the requirements imposed under part 1, to reduce duplication with respect to any information that is required to be provided under any such requirements.

(g) SECRETARIAL ENFORCEMENT AUTHORITY.—

(1) IN GENERAL.—The Secretary of Health and Human Services or the Secretary of Labor (as appropriate) may assess a civil monetary penalty against the administrator of a plan or issuer in connection with the failure of the plan or issuer to comply with the requirements of this section.

(2) AMOUNT OF PENALTY.—

(A) IN GENERAL.—The amount of the penalty to be imposed under paragraph (1) shall not exceed $100 for each day for each participant, beneficiary, or enrollee with respect to which the failure to comply with the requirements of this section occurs.

(B) INCREASE IN AMOUNT.—The amount referred to in subparagraph (A) shall be increased or decreased, for each calendar year that ends after December 31, 2001, by the same percentage as the percentage by which the

medical care expenditure category of the Consumer Price Index for All Urban Consumers (United States city average), published by the Bureau of Labor Statistics, for September of the preceding calendar year has increased or decreased from the such Index for September of 2001.

(3) FAILURE DEFINED.—For purposes of this subsection, a plan or issuer shall have failed to comply with the requirements of this section with respect to a participant, beneficiary, or enrollee if the plan or issuer failed or refused to comply with the requirements of this section within 30 days—

(A) of the date described in subsection (a)(1)(A)(i);

(B) of the date described in subsection (a)(1)(A)(ii); or

(C) of the date on which additional information was requested under subsection (c).

(h) CONFORMING AMENDMENTS.—

(1) Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191a(a)) is amended by striking ''section 711'' and inserting ''section 711 and section 121 of the Bipartisan Patients' Bill of Rights Act of 2001''.

(2) Section 502(b)(3) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(b)(3)) is amended by striking ''733(a)(1))'' and inserting ''733(a)(1)), except with respect to the requirements of section 121 of the Bipartisan Patients' Bill of Rights Act of 2001''.

SEC. 122. INFORMATION ABOUT PROVIDERS.

(a) STUDY.—The Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine for the conduct of a study, and the submission to the Secretary of a report, that includes—

(1) an analysis of information concerning health care professionals that is currently available to patients, consumers, States, and professional societies, nationally and on a State-by-State basis, including patient preferences with respect to information about such professionals and their competencies;

(2) an evaluation of the legal and other barriers to the sharing of information concerning health care professionals; and

(3) recommendations for the disclosure of information on health care professionals, including the competencies and professional qualifications of such practitioners, to better facilitate patient choice, quality improvement, and market competition.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall forward to the appropriate committees of Congress a copy of the report and study conducted under subsection (a).

SEC. 123. STUDY ON THE EFFECT OF PHYSICIAN COMPENSATION METHODS.

(a) STUDY AND REPORT.—

(1) IN GENERAL.—The Secretary shall enter into a contract with the Institute of Medicine for the conduct of a study in accordance with this section, to be submitted to the Secretary and the Secretary of Labor as provided for in paragraph (4).

(2) MATTERS TO BE STUDIED.—The study under paragraph (1) shall include—

(A) a study, including a survey if necessary, of physician compensation arrangements that are utilized in employer-sponsored group health plans (including group health plans sponsored by government and non-government employers) and commercial health insurance products, including—

(i) all types of compensation arrangements, including financial incentive and risk sharing arrangements and arrange-

ments that do not contain such incentives and risk sharing, that reflect the complexity of organizational relationships between health plans and physicians;

(ii) arrangements that are based on factors such as utilization management, cost control, quality improvement, and patient or enrollee satisfaction; and

(iii) arrangements between the plan or issuer and provider, as well as downstream arrangements between providers and sub-contracted providers;

(B) an analysis of the effect of such differing arrangements on physician behavior with respect to the provision of medical care to patients, including whether and how such arrangements affect the quality of patient care and the ability of physicians to provide care that is medically necessary and appropriate.

(3) STUDY DESIGN.—The Secretary shall consult with the Director of the Agency for Healthcare Research and Quality in preparing the scope of work and study design with respect to the contract under paragraph (1).

(4) REPORT.—Not later than 24 months after the date of enactment of this Act, the Secretary shall forward to the appropriate committees of Congress a copy of the report and study conducted under subsection (a).

(b) RESEARCH.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall conduct and support research to develop scientific evidence regarding the effects of differing physician compensation methods on physician behavior with respect to the provision of medical care to patients, particularly issues relating to the quality of patient care and whether patients receive medically necessary and appropriate care.

(2) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

Subtitle C—Right to Hold Health Plans Accountable

SEC. 131. AMENDMENTS TO EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

(a) IN GENERAL.—Part 5 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by inserting after section 503 (29 U.S.C. 1133) the following:

"SEC. 503A. CLAIMS AND INTERNAL APPEALS PROCEDURES FOR GROUP HEALTH PLANS.

"(a) INITIAL CLAIM FOR BENEFITS UNDER GROUP HEALTH PLANS.—

"(1) PROCEDURES.—

"(A) IN GENERAL.—A group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, shall ensure that procedures are in place for—

"(i) making a determination on an initial claim for benefits by a participant or beneficiary (or authorized representative) regarding payment or coverage for items or services under the terms and conditions of the plan or coverage involved, including any cost-sharing amount that the

participant or beneficiary is required to pay with respect to such claim for benefits; and

''(ii) notifying a participant or beneficiary (or authorized representative) and the treating health care professional involved regarding a determination on an initial claim for benefits made under the terms and conditions of the plan or coverage, including any cost-sharing amounts that the participant or beneficiary may be required to make with respect to such claim for benefits, and of the right of the participant or beneficiary to an internal appeal under subsection (b).

''(B) ACCESS TO INFORMATION.—With respect to an initial claim for benefits, the participant or beneficiary (or authorized representative) and the treating health care professional (if any) shall provide the plan or issuer with access to information requested by the plan or issuer that is necessary to make a determination relating to the claim, not later than 5 business days after the date on which the claim is

filed or to meet the applicable timelines under clauses (ii) and (iii) of paragraph (2)(A).

''(C) ORAL REQUESTS.—In the case of a claim for benefits involving an expedited or concurrent determination, a participant or beneficiary (or authorized representative) may make an initial claim for benefits orally, but a group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, may require that the participant or beneficiary (or authorized representative) provide written confirmation of such request in a timely manner.

''(2) TIMELINE FOR MAKING DETERMINATIONS.—

''(A) PRIOR AUTHORIZATION DETERMINATION.—

''(i) IN GENERAL.—A group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that a prior authorization determination on a claim for benefits is made within 14 business days from the date on which the plan or issuer re-

ceives information that is reasonably necessary to enable the plan or issuer to make a determination on the request for prior authorization, but in no case shall such determination be made later than 28 business days after the receipt of the claim for benefits.

''(ii) EXPEDITED DETERMINATION.—Notwithstanding clause (i), a group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, shall maintain procedures for expediting a prior authorization determination on a claim for benefits described in such clause when a request for such an expedited determination is made by a participant or beneficiary (or authorized representative) at any time during the process for making a determination and the treating health care professional substantiates, with the request, that a determination under the procedures described in clause (i) would seriously jeopardize the life or health of the participant or beneficiary. Such determination shall be made

within 72 hours after a request is received by the plan or issuer under this clause.

"(iii) CONCURRENT DETERMINATIONS.—A group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that a concurrent determination on a claim for benefits that results in a discontinuation of inpatient care is made within 24 hours after the receipt of the claim for benefits.

"(B) RETROSPECTIVE DETERMINATION.—A group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that a retrospective determination on a claim for benefits is made within 30 business days of the date on which the plan or issuer receives information that is reasonably necessary to enable the plan or issuer to make a determination on the claim, but in no case shall such determination be made later than 60 business days after the receipt of the claim for benefits.

"(3) NOTICE OF A DENIAL OF A CLAIM FOR BENEFITS.—Written notice of a denial made under an initial claim for benefits shall be issued to the participant or beneficiary (or authorized representative) and the treating health care professional not later than 2 business days after the determination (or within the 72-hour or 24-hour period referred to in clauses (ii) and (iii) of paragraph (2)(A) if applicable).

"(4) REQUIREMENTS OF NOTICE OF DETERMINATIONS.—The written notice of a denial of a claim for benefits determination under paragraph (3) shall include—

"(A) the reasons for the determination (including a summary of the clinical or scientific-evidence based rationale used in making the determination and instruction on obtaining a more complete description written in a manner calculated to be understood by the average participant);

"(B) the procedures for obtaining additional information concerning the determination; and

"(C) notification of the right to appeal the determination and instructions on how to ini-

tiate an appeal in accordance with subsection (b).

"(b) INTERNAL APPEAL OF A DENIAL OF A CLAIM FOR BENEFITS.—

"(1) RIGHT TO INTERNAL APPEAL.—

"(A) IN GENERAL.—A participant or beneficiary (or authorized representative) may appeal any denial of a claim for benefits under subsection (a) under the procedures described in this subsection.

"(B) TIME FOR APPEAL.—A group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, shall ensure that a participant or beneficiary (or authorized representative) has a period of not less than 60 days beginning on the date of a denial of a claim for benefits under subsection (a) in which to appeal such denial under this subsection.

"(C) FAILURE TO ACT.—The failure of a plan or issuer to issue a determination on a claim for benefits under subsection (a) within the applicable timeline established for such a determination under such subsection shall be treated as a denial of a claim for benefits for

purposes of proceeding to internal review under this subsection.

''(D) PLAN WAIVER OF INTERNAL REVIEW.—A group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, may waive the internal review process under this subsection and permit a participant or beneficiary (or authorized representative) to proceed directly to external review under section 503B.

''(2) TIMELINES FOR MAKING DETERMINATIONS.—

''(A) ORAL REQUESTS.—In the case of an appeal of a denial of a claim for benefits under this subsection that involves an expedited or concurrent determination, a participant or beneficiary (or authorized representative) may request such appeal orally, but a group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, may require that the participant or beneficiary (or authorized representative) provide written confirmation of such request in a timely manner.

"(B) ACCESS TO INFORMATION.—With respect to an appeal of a denial of a claim for benefits, the participant or beneficiary (or authorized representative) and the treating health care professional (if any) shall provide the plan or issuer with access to information requested by the plan or issuer that is necessary to make a determination relating to the appeal, not later than 5 business days after the date on which the request for the appeal is filed or to meet the applicable timelines under clauses (ii) and (iii) of subparagraph (C).

"(C) PRIOR AUTHORIZATION DETERMINATIONS.—

"(i) IN GENERAL.—A group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that a determination on an appeal of a denial of a claim for benefits under this subsection is made within 14 business days after the date on which the plan or issuer receives information that is reasonably necessary to enable the plan or issuer to make a determination on the

appeal, but in no case shall such determination be made later than 28 business days after the receipt of the request for the appeal.

"(ii) EXPEDITED DETERMINATION.—Notwithstanding clause (i), a group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, shall maintain procedures for expediting a prior authorization determination on an appeal of a denial of a claim for benefits described in clause (i), when a request for such an expedited determination is made by a participant or beneficiary (or authorized representative) at any time during the process for making a determination and the treating health care professional substantiates, with the request, that a determination under the procedures described in clause (i) would seriously jeopardize the life or health of the participant or beneficiary. Such determination shall be made not later than 72 hours after the request for such

appeal is received by the plan or issuer under this clause.

"(iii) CONCURRENT DETERMINATIONS.—A group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that a concurrent determination on an appeal of a denial of a claim for benefits that results in a discontinuation of inpatient care is made within 24 hours after the receipt of the request for appeal.

"(B) RETROSPECTIVE DETERMINATION.—A group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that a retrospective determination on an appeal of a claim for benefits is made within 30 business days of the date on which the plan or issuer receives necessary information that is reasonably required by the plan or issuer to make a determination on the appeal, but in no case shall such determination be made later than 60 business days after the receipt of the request for the appeal.

"(3) CONDUCT OF REVIEW.—

"(A) IN GENERAL.—A review of a denial of a claim for benefits under this subsection shall be conducted by an individual with appropriate expertise who was not directly involved in the initial determination.

"(B) REVIEW OF MEDICAL DECISIONS BY PHYSICIANS.—A review of an appeal of a denial of a claim for benefits that is based on a lack of medical necessity and appropriateness, or based on an experimental or investigational treatment, or requires an evaluation of medical facts, shall be made by a physician with appropriate expertise, including age-appropriate expertise, who was not involved in the initial determination.

"(4) NOTICE OF DETERMINATION.—

"(A) IN GENERAL.—Written notice of a determination made under an internal appeal of a denial of a claim for benefits shall be issued to the participant or beneficiary (or authorized representative) and the treating health care professional not later than 2 business days after the completion of the review (or within the 72-

hour or 24-hour period referred to in paragraph (2) if applicable).

''(B) FINAL DETERMINATION.—The decision by a plan or issuer under this subsection shall be treated as the final determination of the plan or issuer on a denial of a claim for benefits. The failure of a plan or issuer to issue a determination on an appeal of a denial of a claim for benefits under this subsection within the applicable timeline established for such a determination shall be treated as a final determination on an appeal of a denial of a claim for benefits for purposes of proceeding to external review under section 503B.

''(C) REQUIREMENTS OF NOTICE.—With respect to a determination made under this subsection, the notice described in subparagraph (A) shall include—

''(i) the reasons for the determination (including a summary of the clinical or scientific-evidence based rationale used in making the determination and instruction on obtaining a more complete description written in a manner calculated to be understood by the average participant);

''(ii) the procedures for obtaining additional information concerning the determination; and

''(iii) notification of the right to an independent external review under section 503B and instructions on how to initiate such a review.

''(c) DEFINITIONS.—The definitions contained in section 503B(i) shall apply for purposes of this section.

''SEC. 503B. INDEPENDENT EXTERNAL APPEALS PROCEDURES FOR GROUP HEALTH PLANS.

''(a) RIGHT TO EXTERNAL APPEAL.—A group health plan, and a health insurance issuer that offers health insurance coverage in connection with a group health plan, shall provide in accordance with this section participants and beneficiaries (or authorized representatives) with access to an independent external review for any denial of a claim for benefits.

''(b) INITIATION OF THE INDEPENDENT EXTERNAL REVIEW PROCESS.—

''(1) TIME TO FILE.—A request for an independent external review under this section shall be filed with the plan or issuer not later than 60 business days after the date on which the participant or beneficiary receives notice of the denial under sec-

tion 503A(b)(4) or the date on which the internal review is waived by the plan or issuer under section 503A(b)(1)(D).

''(2) FILING OF REQUEST.—

''(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, a group health plan, and a health insurance issuer that offers health insurance coverage in connection with a group health plan, may—

''(i) except as provided in subparagraph (B)(i), require that a request for review be in writing;

''(ii) limit the filing of such a request to the participant or beneficiary involved (or an authorized representative);

''(iii) except if waived by the plan or issuer under section 503A(b)(1)(D), condition access to an independent external review under this section upon a final determination of a denial of a claim for benefits under the internal review procedure under section 503A;

''(iv) except as provided in subparagraph (B)(ii), require payment of a filing

fee to the plan or issuer of a sum that does not exceed $50; and

''(v) require that a request for review include the consent of the participant or beneficiary (or authorized representative) for the release of medical information or records of the participant or beneficiary to the qualified external review entity for purposes of conducting external review activities.

''(B) REQUIREMENTS AND EXCEPTION RELATING TO GENERAL RULE.—

''(i) ORAL REQUESTS PERMITTED IN EXPEDITED OR CONCURRENT CASES.—In the case of an expedited or concurrent external review as provided for under subsection (e), the request may be made orally. In such case a written confirmation of such request shall be made in a timely manner. Such written confirmation shall be treated as a consent for purposes of subparagraph (A)(v).

''(ii) EXCEPTION TO FILING FEE REQUIREMENT.—

"(I) INDIGENCY.—Payment of a filing fee shall not be required under subparagraph (A)(iv) where there is a certification (in a form and manner specified in guidelines established by the Secretary) that the participant or beneficiary is indigent (as defined in such guidelines). In establishing guidelines under this subclause, the Secretary shall ensure that the guidelines relating to indigency are consistent with the poverty guidelines used by the Secretary of Health and Human Services under title XIX of the Social Security Act.

"(II) FEE NOT REQUIRED.—Payment of a filing fee shall not be required under subparagraph (A)(iv) if the plan or issuer waives the internal appeals process under section 503A(b)(1)(D).

"(III) REFUNDING OF FEE.—The filing fee paid under subparagraph (A)(iv) shall be refunded if the determination under the independent

external review is to reverse the denial which is the subject of the review.

''(IV) INCREASE IN AMOUNT.—The amount referred to in subclause (I) shall be increased or decreased, for each calendar year that ends after December 31, 2002, by the same percentage as the percentage by which the Consumer Price Index for All Urban Consumers (United States city average), published by the Bureau of Labor Statistics, for September of the preceding calendar year has increased or decreased from the such Index for September of 2002.

''(c) REFERRAL TO QUALIFIED EXTERNAL REVIEW ENTITY UPON REQUEST.—

''(1) IN GENERAL.—Upon the filing of a request for independent external review with the group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, the plan or issuer shall refer such request to a qualified external review entity selected in accordance with this section.

''(2) ACCESS TO PLAN OR ISSUER AND HEALTH PROFESSIONAL INFORMATION.—With respect to an independent external review conducted under this section, the participant or beneficiary (or authorized representative), the plan or issuer, and the treating health care professional (if any) shall provide the external review entity with access to information requested by the external review entity that is necessary to conduct a review under this section, as determined by the entity, not later than 5 business days after the date on which a request is referred to the qualified external review entity under paragraph (1), or earlier as determined appropriate by the entity to meet the applicable timelines under clauses (ii) and (iii) of subsection (e)(1)(A).

''(3) SCREENING OF REQUESTS BY QUALIFIED EXTERNAL REVIEW ENTITIES.—

''(A) IN GENERAL.—With respect to a request referred to a qualified external review entity under paragraph (1) relating to a denial of a claim for benefits, the entity shall refer such request for the conduct of an independent medical review unless the entity determines that—

''(i) any of the conditions described in subsection (b)(2)(A) have not been met;

"(ii) the thresholds described in subparagraph (B) have not been met;

"(iii) the denial of the claim for benefits does not involve a medically reviewable decision under subsection (d)(2);

"(iv) the denial of the claim for benefits relates to a decision regarding whether an individual is a participant or beneficiary who is enrolled under the terms of the plan or coverage (including the applicability of any waiting period under the plan or coverage); or

"(v) the denial of the claim for benefits is a decision as to the application of cost-sharing requirements or the application of a specific exclusion or express limitation on the amount, duration, or scope of coverage of items or services under the terms and conditions of the plan or coverage unless the decision is a denial described in subsection (d)(2);

Upon making a determination that any of clauses (i) through (v) applies with respect to the request, the entity shall determine that the denial of a claim for benefits involved is not eli-

gible for independent medical review under subsection (d), and shall provide notice in accordance with subparagraph (D).

''(B) THRESHOLDS.—

''(i) IN GENERAL.—The thresholds described in this subparagraph are that—

''(I) the total amount payable under the plan or coverage for the item or service that was the subject of such denial exceeds $100; or

''(II) a physician has asserted in writing that there is a significant risk of placing the life, health, or development of the participant or beneficiary in jeopardy if the denial of the claim for benefits is sustained.

''(ii) THRESHOLDS NOT APPLIED.—The thresholds described in this subparagraph shall not apply if the plan or issuer involved waives the internal appeals process with respect to the denial of a claim for benefits involved under section 503A(b)(1)(D).

''(C) PROCESS FOR MAKING DETERMINATIONS.—

"(i) NO DEFERENCE TO PRIOR DETERMINATIONS.—In making determinations under subparagraph (A), there shall be no deference given to determinations made by the plan or issuer under section 503A or the recommendation of a treating health care professional (if any).

"(ii) USE OF APPROPRIATE PERSONNEL.—A qualified external review entity shall use appropriately qualified personnel to make determinations under this section.

"(D) NOTICES AND GENERAL TIMELINES FOR DETERMINATION.—

"(i) NOTICE IN CASE OF DENIAL OF REFERRAL.—If the entity under this paragraph does not make a referral to an independent medical reviewer, the entity shall provide notice to the plan or issuer, the participant or beneficiary (or authorized representative) filing the request, and the treating health care professional (if any) that the denial is not subject to independent medical review. Such notice—

''(I) shall be written (and, in addition, may be provided orally) in a manner calculated to be understood by an average participant;

''(II) shall include the reasons for the determination; and

''(III) include any relevant terms and conditions of the plan or coverage.

''(ii) GENERAL TIMELINE FOR DETERMINATIONS.—Upon receipt of information under paragraph (2), the qualified external review entity, and if required the independent medical reviewer, shall make a determination within the overall timeline that is applicable to the case under review as described in subsection (e), except that if the entity determines that a referral to an independent medical reviewer is not required, the entity shall provide notice of such determination to the participant or beneficiary (or authorized representative) within 2 business days of such determination.

''(d) INDEPENDENT MEDICAL REVIEW.—

''(1) IN GENERAL.—If a qualified external review entity determines under subsection (c) that a denial of a claim for benefits is eligible for independent medical review, the entity shall refer the denial involved to an independent medical reviewer for the conduct of an independent medical review under this subsection.

''(2) MEDICALLY REVIEWABLE DECISIONS.—A denial described in this paragraph is one for which the item or service that is the subject of the denial would be a covered benefit under the terms and conditions of the plan or coverage but for one (or more) of the following determinations:

''(A) DENIALS BASED ON MEDICAL NECESSITY AND APPROPRIATENESS.—The basis of the determination is that the item or service is not medically necessary and appropriate.

''(B) DENIALS BASED ON EXPERIMENTAL OR INVESTIGATIONAL TREATMENT.—The basis of the determination is that the item or service is experimental or investigational.

''(C) DENIALS OTHERWISE BASED ON AN EVALUATION OF MEDICAL FACTS.—A determination that the item or service or condition is not covered but an evaluation of the medical

facts by a health care professional in the specific case involved is necessary to determine whether the item or service or condition is required to be provided under the terms and conditions of the plan or coverage.

''(3) INDEPENDENT MEDICAL REVIEW DETERMINATION.—

''(A) IN GENERAL.—An independent medical reviewer under this section shall make a new independent determination with respect to—

''(i) whether the item or service or condition that is the subject of the denial is covered under the terms and conditions of the plan or coverage; and

''(ii) based upon an affirmative determination under clause (i), whether or not the denial of a claim for a benefit that is the subject of the review should be upheld or reversed.

''(B) STANDARD FOR DETERMINATION.—The independent medical reviewer's determination relating to the medical necessity and appropriateness, or the experimental or investigation nature, or the evaluation of the medical

facts of the item, service, or condition shall be based on the medical condition of the participant or beneficiary (including the medical records of the participant or beneficiary) and the valid, relevant scientific evidence and clinical evidence, including peer-reviewed medical literature or findings and including expert consensus.

''(C) NO COVERAGE FOR EXCLUDED BENEFITS.—Nothing in this subsection shall be construed to permit an independent medical reviewer to require that a group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, provide coverage for items or services that are specifically excluded or expressly limited under the plan or coverage and that are not covered regardless of any determination relating to medical necessity and appropriateness, experimental or investigational nature of the treatment, or an evaluation of the medical facts in the case involved.

''(D) EVIDENCE AND INFORMATION TO BE USED IN MEDICAL REVIEWS.—In making a determination under this subsection, the inde-

pendent medical reviewer shall also consider appropriate and available evidence and information, including the following:

''(i) The determination made by the plan or issuer with respect to the claim upon internal review and the evidence or guidelines used by the plan or issuer in reaching such determination.

''(ii) The recommendation of the treating health care professional and the evidence, guidelines, and rationale used by the treating health care professional in reaching such recommendation.

''(iii) Additional evidence or information obtained by the reviewer or submitted by the plan, issuer, participant or beneficiary (or an authorized representative), or treating health care professional.

''(iv) The plan or coverage document.

''(E) INDEPENDENT DETERMINATION.—In making the determination, the independent medical reviewer shall—

''(i) consider the claim under review without deference to the determinations made by the plan or issuer under section

503A or the recommendation of the treating health care professional (if any); and

"(ii) consider, but not be bound by the definition used by the plan or issuer of 'medically necessary and appropriate', or 'experimental or investigational', or other equivalent terms that are used by the plan or issuer to describe medical necessity and appropriateness or experimental or investigational nature of the treatment.

"(F) DETERMINATION OF INDEPENDENT MEDICAL REVIEWER.—An independent medical reviewer shall, in accordance with the deadlines described in subsection (e), prepare a written determination to uphold or reverse the denial under review and, in the case of a reversal, the timeframe within which the plan or issuer shall authorize coverage to comply with the determination. Such written determination shall include the specific reasons of the reviewer for such determination, including a summary of the clinical or scientific-evidence based rationale used in making the determination. The reviewer may provide the plan or issuer and the treating health care professional with additional rec-

ommendations in connection with such a determination, but any such recommendations shall not be treated as part of the determination.

''(e) TIMELINES AND NOTIFICATIONS.—

''(1) TIMELINES FOR INDEPENDENT MEDICAL REVIEW.—

''(A) PRIOR AUTHORIZATION DETERMINATION.—

''(i) IN GENERAL.—The independent medical reviewer (or reviewers) shall make a determination on a denial of a claim for benefits that is referred to the reviewer under subsection (c)(3) not later than 14 business days after the receipt of information under subsection (c)(2) if the review involves a prior authorization of items or services.

''(ii) EXPEDITED DETERMINATION.—Notwithstanding clause (i), the independent medical reviewer (or reviewers) shall make an expedited determination on a denial of a claim for benefits described in clause (i), when a request for such an expedited determination is made by a participant or beneficiary (or authorized rep-

resentative) at any time during the process for making a determination, and the treating health care professional substantiates, with the request, that a determination under the timeline described in clause (i) would seriously jeopardize the life or health of the participant or beneficiary. Such determination shall be made not later than 72 hours after the receipt of information under subsection (c)(2).

''(iii) CONCURRENT DETERMINATION.—Notwithstanding clause (i), a review described in such subclause shall be completed not later than 24 hours after the receipt of information under subsection (c)(2) if the review involves a discontinuation of inpatient care.

''(B) RETROSPECTIVE DETERMINATION.—The independent medical reviewer (or reviewers) shall complete a review in the case of a retrospective determination on an appeal of a denial of a claim for benefits that is referred to the reviewer under subsection (c)(3) not later than 30 business days after the receipt of information under subsection (c)(2).

''(2) NOTIFICATION OF DETERMINATION.—The external review entity shall ensure that the plan or issuer, the participant or beneficiary (or authorized representative) and the treating health care professional (if any) receives a copy of the written determination of the independent medical reviewer prepared under subsection (d)(3)(F). Nothing in this paragraph shall be construed as preventing an entity or reviewer from providing an initial oral notice of the reviewer's determination.

''(3) FORM OF NOTICES.—Determinations and notices under this subsection shall be written in a manner calculated to be understood by an average participant.

''(4) TERMINATION OF EXTERNAL REVIEW PROCESS IF APPROVAL OF A CLAIM FOR BENEFITS DURING PROCESS.—

''(A) IN GENERAL.—If a plan or issuer—

''(i) reverses a determination on a denial of a claim for benefits that is the subject of an external review under this section and authorizes coverage for the claim or provides payment of the claim; and

''(ii) provides notice of such reversal to the participant or beneficiary (or au-

thorized representative) and the treating health care professional (if any), and the external review entity responsible for such review,

the external review process shall be terminated with respect to such denial and any filing fee paid under subsection (b)(2)(A)(iv) shall be refunded.

''(B) TREATMENT OF TERMINATION.—An authorization of coverage under subparagraph (A) by the plan or issuer shall be treated as a written determination to reverse a denial under section (d)(3)(F) for purposes of liability under section 502(n)(1)(B).

''(f) COMPLIANCE.—

''(1) APPLICATION OF DETERMINATIONS.—

''(A) EXTERNAL REVIEW DETERMINATIONS BINDING ON PLAN.—The determinations of an external review entity and an independent medical reviewer under this section shall be binding upon the plan or issuer involved.

''(B) COMPLIANCE WITH DETERMINATION.—If the determination of an independent medical reviewer is to reverse the denial, the plan or issuer, upon the receipt of such deter-

mination, shall authorize coverage to comply with the medical reviewer's determination in accordance with the timeframe established by the medical reviewer under subsection (d)(3)(F).

''(2) FAILURE TO COMPLY.—If a plan or issuer fails to comply with the timeframe established under paragraph (1)(B) with respect to a participant or beneficiary, where such failure to comply is caused by the plan or issuer, the participant or beneficiary may obtain the items or services involved (in a manner consistent with the determination of the independent external reviewer) from any provider regardless of whether such provider is a participating provider under the plan or coverage.

''(3) REIMBURSEMENT.—

''(A) IN GENERAL.—Where a participant or beneficiary obtains items or services in accordance with paragraph (2), the plan or issuer involved shall provide for reimbursement of the costs of such items or services. Such reimbursement shall be made to the treating health care professional or to the participant or beneficiary (in the case of a participant or beneficiary who pays for the costs of such items or services).

''(B) AMOUNT.—The plan or issuer shall fully reimburse a professional, participant or beneficiary under subparagraph (A) for the total costs of the items or services provided (regardless of any plan limitations that may apply to the coverage of such items or services) so long as—

''(i) the items or services would have been covered under the terms of the plan or coverage if provided by the plan or issuer; and

''(ii) the items or services were provided in a manner consistent with the determination of the independent medical reviewer.

''(4) FAILURE TO REIMBURSE.—Where a plan or issuer fails to provide reimbursement to a professional, participant or beneficiary in accordance with this subsection, the professional, participant or beneficiary may commence a civil action (or utilize other remedies available under law) to recover only the amount of any such reimbursement that is unpaid and any necessary legal costs or expenses (including attorneys' fees) incurred in recovering such reimbursement.

''(g) QUALIFICATIONS OF INDEPENDENT MEDICAL REVIEWERS.—

''(1) IN GENERAL.—In referring a denial to 1 or more individuals to conduct independent medical review under subsection (c), the qualified external review entity shall ensure that—

''(A) each independent medical reviewer meets the qualifications described in paragraphs (2) and (3);

''(B) with respect to each review at least 1 such reviewer meets the requirements described in paragraphs (4) and (5); and

''(C) compensation provided by the entity to the reviewer is consistent with paragraph (6).

''(2) LICENSURE AND EXPERTISE.—

''(A) IN GENERAL.—Subject to subparagraph (B), each independent medical reviewer shall be a physician (who may be an allopathic or osteopathic physician) or health care professional who—

''(i) is appropriately credentialed or licensed in 1 or more States to deliver health care services; and

"(ii) typically treats the diagnosis or condition or provides the type of treatment under review.

"(B) PHYSICIAN REVIEW.—In referring a denial for independent medical review under subsection (c), the qualified external review entity shall ensure that, in the case of the review of treatment that is recommended or provided by a physician, such referral may be made only to a physician for such independent medical review.

"(3) INDEPENDENCE.—

"(A) IN GENERAL.—Subject to subparagraph (B), each independent medical reviewer in a case shall—

"(i) not be a related party (as defined in paragraph (7));

"(ii) not have a material familial, financial, or professional relationship with such a party; and

"(iii) not otherwise have a conflict of interest with such a party (as determined under regulations).

"(B) EXCEPTION.—Nothing in this subparagraph (A) shall be construed to—

"(i) prohibit an individual, solely on the basis of affiliation with the plan or issuer, from serving as an independent medical reviewer if—

"(I) a non-affiliated individual is not reasonably available;

"(II) the affiliated individual is not involved in the provision of items or services in the case under review;

"(III) the fact of such an affiliation is disclosed to the plan or issuer and the participant or beneficiary (or authorized representative) and neither party objects; and

"(IV) the affiliated individual is not an employee of the plan or issuer and does not provide services exclusively or primarily to or on behalf of the plan or issuer;

"(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as an independent medical reviewer if the affiliation is disclosed to the plan or issuer and the participant or beneficiary

(or authorized representative), and neither party objects; or

"(iii) prohibit receipt of compensation by an independent medical reviewer from an entity if the compensation is provided consistent with paragraph (6).

"(4) PRACTICING HEALTH CARE PROFESSIONAL IN SAME FIELD.—

"(A) IN GENERAL.—The requirement of this paragraph with respect to a reviewer in a case involving treatment, or the provision of items or services, by—

"(i) a physician, is that the reviewer be a practicing physician of the same or similar specialty as a physician who typically treats the diagnosis or condition or provides such treatment in the case under review; or

"(ii) a health care professional (other than a physician), is that the reviewer be a practicing physician or, if determined appropriate by the qualified external review entity, a health care professional (other than a physician), of the same or similar specialty as the health care professional

who typically treats the diagnosis or condition or provides the treatment in the case under review.

''(B) PRACTICING DEFINED.—For purposes of this paragraph, the term 'practicing' means, with respect to an individual who is a physician or other health care professional that the individual provides health care services to individual patients on average at least 1 day per week.

''(5) AGE-APPROPRIATE EXPERTISE.—The independent medical reviewer shall have expertise under paragraph (2) that is age-appropriate to the participant or beneficiary involved.

''(6) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by a qualified external review entity to an independent medical reviewer in connection with a review under this section shall—

''(A) not exceed a reasonable level; and

''(B) not be contingent on the decision rendered by the reviewer.

''(7) RELATED PARTY DEFINED.—For purposes of this section, the term 'related party' means, with respect to a denial of a claim under a plan or cov-

erage relating to a participant or beneficiary, any of the following:

"(A) The plan, plan sponsor, or issuer involved, or any fiduciary, officer, director, or employee of such plan, plan sponsor, or issuer.

"(B) The participant or beneficiary (or authorized representative).

"(C) The health care professional that provides the items of services involved in the denial.

"(D) The institution at which the items or services (or treatment) involved in the denial are provided.

"(E) The manufacturer of any drug or other item that is included in the items or services involved in the denial.

"(F) Any other party determined under any regulations to have a substantial interest in the denial involved.

"(h) QUALIFIED EXTERNAL REVIEW ENTITIES.—

"(1) SELECTION OF QUALIFIED EXTERNAL REVIEW ENTITIES.—

"(A) LIMITATION ON PLAN OR ISSUER SELECTION.—The Secretary shall implement procedures with respect to the selection of qualified

external review entities by a plan or issuer to assure that the selection process among qualified external review entities will not create any incentives for external review entities to make a decision in a biased manner.

''(B) STATE AUTHORITY WITH RESPECT TO QUALIFIED EXTERNAL REVIEW ENTITIES FOR HEALTH INSURANCE ISSUERS.—With respect to health insurance issuers offering health insurance coverage in a State, the State may provide for the designation or selection of qualified external review entities in a manner determined by the State to assure an unbiased determination in conducting external review activities. In conducting reviews under this section, an entity designated or selected under this subparagraph shall comply with provisions of this section.

''(2) CONTRACT WITH QUALIFIED EXTERNAL REVIEW ENTITY.—Except as provided in paragraph (1)(B), the external review process of a plan or issuer under this section shall be conducted under a contract between the plan or issuer and 1 or more qualified external review entities (as defined in paragraph (4)(A)).

''(3) TERMS AND CONDITIONS OF CONTRACT.—The terms and conditions of a contract under paragraph (2) shall—

''(A) be consistent with the standards the Secretary shall establish to assure there is no real or apparent conflict of interest in the conduct of external review activities; and

''(B) provide that the costs of the external review process shall be borne by the plan or issuer.

Subparagraph (B) shall not be construed as applying to the imposition of a filing fee under subsection (b)(2)(A)(iv) or costs incurred by the participant or beneficiary (or authorized representative) or treating health care professional (if any) in support of the review, including the provision of additional evidence or information.

''(4) QUALIFICATIONS.—

''(A) IN GENERAL.—In this section, the term 'qualified external review entity' means, in relation to a plan or issuer, an entity that is initially certified (and periodically recertified) under subparagraph (C) as meeting the following requirements:

''(i) The entity has (directly or through contracts or other arrangements) sufficient medical, legal, and other expertise and sufficient staffing to carry out duties of a qualified external review entity under this section on a timely basis, including making determinations under subsection (b)(2)(A) and providing for independent medical reviews under subsection (d).

''(ii) The entity is not a plan or issuer or an affiliate or a subsidiary of a plan or issuer, and is not an affiliate or subsidiary of a professional or trade association of plans or issuers or of health care providers.

''(iii) The entity has provided assurances that it will conduct external review activities consistent with the applicable requirements of this section and standards specified in subparagraph (C), including that it will not conduct any external review activities in a case unless the independence requirements of subparagraph (B) are met with respect to the case.

''(iv) The entity has provided assurances that it will provide information in a timely manner under subparagraph (D).

''(v) The entity meets such other requirements as the Secretary provides by regulation.

''(B) INDEPENDENCE REQUIREMENTS.—

''(i) IN GENERAL.—Subject to clause (ii), an entity meets the independence requirements of this subparagraph with respect to any case if the entity—

''(I) is not a related party (as defined in subsection (g)(7));

''(II) does not have a material familial, financial, or professional relationship with such a party; and

''(III) does not otherwise have a conflict of interest with such a party (as determined under regulations).

''(ii) EXCEPTION FOR REASONABLE COMPENSATION.—Nothing in clause (i) shall be construed to prohibit receipt by a qualified external review entity of compensation from a plan or issuer for the conduct of external review activities under

this section if the compensation is provided consistent with clause (iii).

''(iii) LIMITATIONS ON ENTITY COMPENSATION.—Compensation provided by a plan or issuer to a qualified external review entity in connection with reviews under this section shall—

''(I) not exceed a reasonable level; and

''(II) not be contingent on the decision rendered by the entity or by any independent medical reviewer.

''(C) CERTIFICATION AND RECERTIFICATION PROCESS.—

''(i) IN GENERAL.—The initial certification and recertification of a qualified external review entity shall be made—

''(I) under a process that is recognized or approved by the Secretary; or

''(II) by a qualified private standard-setting organization that is approved by the Secretary under clause (iii).

''(ii) PROCESS.—The Secretary shall not recognize or approve a process under clause (i)(I) unless the process applies standards (as promulgated in regulations) that ensure that a qualified external review entity—

''(I) will carry out (and has carried out, in the case of recertification) the responsibilities of such an entity in accordance with this section, including meeting applicable deadlines;

''(II) will meet (and has met, in the case of recertification) appropriate indicators of fiscal integrity;

''(III) will maintain (and has maintained, in the case of recertification) appropriate confidentiality with respect to individually identifiable health information obtained in the course of conducting external review activities; and

''(IV) in the case recertification, shall review the matters described in clause (iv).

''(iii) APPROVAL OF QUALIFIED PRIVATE STANDARD-SETTING ORGANIZATIONS.—For purposes of clause (i)(II), the Secretary may approve a qualified private standard-setting organization if the Secretary finds that the organization only certifies (or recertifies) external review entities that meet at least the standards required for the certification (or recertification) of external review entities under clause (ii).

''(iv) CONSIDERATIONS IN RECERTIFICATIONS.—In conducting recertifications of a qualified external review entity under this paragraph, the Secretary or organization conducting the recertification shall review compliance of the entity with the requirements for conducting external review activities under this section, including the following:

''(I) Provision of information under subparagraph (D).

''(II) Adherence to applicable deadlines (both by the entity and by

independent medical reviewers it refers cases to).

''(III) Compliance with limitations on compensation (with respect to both the entity and independent medical reviewers it refers cases to).

''(IV) Compliance with applicable independence requirements.

''(v) PERIOD OF CERTIFICATION OR RECERTIFICATION.—A certification or recertification provided under this paragraph shall extend for a period not to exceed 5 years.

''(vi) REVOCATION.—A certification or recertification under this paragraph may be revoked by the Secretary or by the organization providing such certification upon a showing of cause.

''(D) PROVISION OF INFORMATION.—

''(i) IN GENERAL.—A qualified external review entity shall provide to the Secretary, in such manner and at such times as the Secretary may require, such information (relating to the denials which have been referred to the entity for the conduct

of external review under this section) as the Secretary determines appropriate to assure compliance with the independence and other requirements of this section to monitor and assess the quality of its external review activities and lack of bias in making determinations. Such information shall include information described in clause (ii) but shall not include individually identifiable medical information.

''(ii) INFORMATION TO BE INCLUDED.—The information described in this subclause with respect to an entity is as follows:

''(I) The number and types of denials for which a request for review has been received by the entity.

''(II) The disposition by the entity of such denials, including the number referred to a independent medical reviewer and the reasons for such dispositions (including the application of exclusions), on a plan or issuer-specific basis and on a health care specialty-specific basis.

''(III) The length of time in making determinations with respect to such denials.

''(IV) Updated information on the information required to be submitted as a condition of certification with respect to the entity's performance of external review activities.

''(iii) INFORMATION TO BE PROVIDED TO CERTIFYING ORGANIZATION.—

''(I) IN GENERAL.—In the case of a qualified external review entity which is certified (or recertified) under this subsection by a qualified private standard-setting organization, at the request of the organization, the entity shall provide the organization with the information provided to the Secretary under clause (i).

''(II) ADDITIONAL INFORMATION.—Nothing in this subparagraph shall be construed as preventing such an organization from requiring additional information as a condition of

certification or recertification of an entity.

''(iv) USE OF INFORMATION.—

''(I) IN GENERAL.—Information provided under this subparagraph may be used by the Secretary and qualified private standard-setting organizations to conduct oversight of qualified external review entities, including recertification of such entities, and shall be made available to the public in an appropriate manner.

''(II) REPORT TO CONGRESS.—Not later than 2 years after the date on which the Bipartisan Patients' Bill of Rights Act of 2001 takes effect under section 501 of such Act, and every 2 years thereafter, the Secretary, in consultation with the Secretary of Health and Human Services, shall prepare and submit to the appropriate committees of Congress, a report that contains—

"(aa) a summary of the information provided to the Secretary under clause (ii);

"(bb) a description of the effect that the appeals process established under this section and section 503A had on the access of individuals to health insurance and health care;

"(cc) a description of the effect on health care costs associated with the implementation of the appeals process described in item (bb); and

"(dd) a description of the quality and consistency of determinations by qualified external review entities.

"(III) RECOMMENDATIONS.—The Secretary may from time to time submit recommendations to Congress with respect to proposed modifications to the appeals process based on the reports submitted under subclause (II).

''(E) LIMITATION ON LIABILITY.—No qualified external review entity having a contract with a plan or issuer, and no person who is employed by any such entity or who furnishes professional services to such entity (including as an independent medical reviewer), shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this section, to be civilly liable under any law of the United States or of any State (or political subdivision thereof) if there was no actual malice or gross misconduct in the performance of such duty, function, or activity.

''(i) DEFINITIONS.—In this section:

''(1) AUTHORIZED REPRESENTATIVE.—The term 'authorized representative' means, with respect to a participant or beneficiary—

''(A) a person to whom a participant or beneficiary has given express written consent to represent the participant or beneficiary in any proceeding under this section;

''(B) a person authorized by law to provide substituted consent for the participant or beneficiary; or

"(C) a family member of the participant or beneficiary (or the estate of the participant or beneficiary) or the participant's or beneficiary's treating health care professional when the participant or beneficiary is unable to provide consent.

"(2) CLAIM FOR BENEFITS.—The term 'claim for benefits' means any request by a participant or beneficiary (or authorized representative) for benefits (including requests that are subject to authorization of coverage or utilization review), for eligibility, or for payment in whole or in part, for an item or service under a group health plan or health insurance coverage offered by a health insurance issuer in connection with a group health plan.

"(3) GROUP HEALTH PLAN.—The term 'group health plan' shall have the meaning given such term in section 733(a). In applying this paragraph, excepted benefits described in section 733(c) shall not be treated as benefits consisting of medical care.

"(4) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' has the meaning given such term in section 733(b)(1). In applying this paragraph, excepted benefits described in sec-

tion 733(c) shall not be treated as benefits consisting of medical care.

''(5) HEALTH INSURANCE ISSUER.—The term 'health insurance issuer' has the meaning given such term in section 733(b)(2).

''(6) PRIOR AUTHORIZATION DETERMINATION.—The term 'prior authorization determination' means a determination by the group health plan or health insurance issuer offering health insurance coverage in connection with a group health plan prior to the provision of the items and services as a condition of coverage of the items and services under the terms and conditions of the plan or coverage.

''(7) TREATING HEALTH CARE PROFESSIONAL.—The term 'treating health care professional' with respect to a group health plan, health insurance issuer or provider sponsored organization means a physician (medical doctor or doctor of osteopathy) or other health care practitioner who is acting within the scope of his or her State licensure or certification for the delivery of health care services and who is primarily responsible for delivering those services to the participant or beneficiary.

''(8) UTILIZATION REVIEW.—The term 'utilization review' with respect to a group health plan or health insurance coverage means procedures used in the determination of coverage for a participant or beneficiary, such as procedures to evaluate the medical necessity, appropriateness, efficacy, quality, or efficiency of health care services, procedures or settings, and includes prospective review, concurrent review, second opinions, case management, discharge planning, or retrospective review.''.

(b) CONFORMING AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by inserting after the item relating to section 503 the following:

''Sec. 503A. Claims and internal appeals procedures for group health plans.
''Sec. 503B. Independent external appeals procedures for group health plans.''.

SEC. 132. ENFORCEMENT.

Section 502(c) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(c)) is amended by adding at the end the following:

''(8) The Secretary may assess a civil penalty against any plan of up to $10,000 for the plan's failure or refusal to comply with any deadline applicable under section 503B or any determination under such section, except that in any case in which coverage was not approved by the plan in accordance with the determination of an independent

external reviewer, the Secretary shall assess a civil penalty of $10,000 against the plan and the plan shall pay such penalty to the participant or beneficiary involved.''.

Subtitle D—Remedies

SEC. 141. AVAILABILITY OF COURT REMEDIES.

(a) IN GENERAL.—Section 502 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132) is amended by adding at the end the following:

''(n) CAUSE OF ACTION RELATING TO DENIAL OF A CLAIM FOR HEALTH BENEFITS.—

''(1) IN GENERAL.—

''(A) FAILURE TO COMPLY WITH EXTERNAL MEDICAL REVIEW.—With respect to an action commenced by a participant or beneficiary (or the estate of the participant or beneficiary) in connection with a claim for benefits under a group health plan, if—

''(i) a designated decision-maker described in paragraph (2) fails to exercise ordinary care in approving coverage pursuant to the written determination of an independent medical reviewer under section 503B(d)(3)(F) that reverses a denial of the claim for benefits; and

"(ii) the failure described in clause (i) is the proximate cause of substantial harm (as defined in paragraph (10)(G)) to the participant or beneficiary;

such designated decision-maker shall be liable to the participant or beneficiary (or the estate) for economic and noneconomic damages in connection with such failure and such injury or death (subject to paragraph (4)).

"(B) WRONGFUL DETERMINATION RESULTING IN DELAY IN PROVIDING BENEFITS.—With respect to an action commenced by a participant or beneficiary (or the estate of the participant or beneficiary) in connection with a claim for benefits under a group health plan, if—

"(i) a designated decision-maker described in paragraph (2)—

"(I) fails to exercise ordinary care in making a determination denying the claim for benefits under section 503A(a) (relating to an initial claim for benefits); or

"(II) fails to exercise ordinary care in making a determination deny-

ing the claim for benefits under section 503A(b) (relating to an internal appeal);

''(ii) the denial described in clause (i) is reversed by an independent medical reviewer under section 503B(d) or 503B(e)(4)(B); and

''(iii) the delay attributable to the failure described in clause (i) is the proximate cause of substantial harm to, or the wrongful death of, the participant or beneficiary;

such designated decision-maker shall be liable to the participant or beneficiary (or the estate) for economic and noneconomic damages in connection with such failure and such injury or death (subject to paragraph (4)).

''(C) LIMITATION ON LIABILITY BASED ON APPOINTMENT OF DESIGNATED DECISION-MAKER.—If a plan sponsor or named fiduciary appoints a designated decision-maker in accordance with paragraph (2), the plan sponsor or named fiduciary, or any other person or group health plan (or their employees) associated with the plan sponsor or named fiduciary, shall not be liable under this paragraph. The appoint-

ment of a designated decision-maker in accordance with paragraph (2) shall not affect the liability of the appointing plan sponsor or named fiduciary for the failure of the plan sponsor or named fiduciary to comply with any other requirement of this title.

''(2) DESIGNATED DECISION-MAKER.—

''(A) APPOINTMENT.—

''(i) IN GENERAL.—The plan sponsor or named fiduciary of a group health plan shall, in accordance with this paragraph, designate one or more persons to serve as a designated decision-maker with respect to causes of action described in subparagraphs (A) and (B) of paragraph (1), except that—

''(I) with respect to health insurance coverage offered in connection with a group health plan, the health insurance issuer shall be the designated decision-maker unless the plan sponsor and the issuer specifically agree in writing (on a form to be prescribed by the Secretary) to sub-

stitute another person as the designated decision-maker; or

''(II) with respect to the designation of a person other than a plan sponsor or health insurance issuer, such person shall satisfy the requirements of subparagraph (D).

''(ii) PLAN DOCUMENTS.—The designated decision-maker shall be specifically designated as such in the written instruments of the plan (under section 402(a)) and be identified as required under section 121(b)(14) of the Bipartisan Patients' Bill of Rights Act of 2001.

''(B) AUTHORITY.—A designated decision-maker appointed under subparagraph (A) shall have the exclusive authority under the group health plan—

''(i) to make determinations with respect to a claim for benefits under section 503A(a) (relating to an initial claim for benefits);

''(ii) to make final determinations under section 503A(b) (relating to an internal appeal); or

"(iii) to approve coverage pursuant to the written determination of independent medical reviewers under section 503B.

"(C) ALLOCATION OF RESPONSIBILITY.—Responsibility may be allocated among different designated decision-makers with respect to—

"(i) for purposes of paragraph (1)(A), the approval of coverage under section 503B;

"(ii) for purposes of paragraph (1)(B), making determinations on a claim for benefits under section 503A(a) (relating to an initial claim for benefits); and

"(iii) for purposes of paragraph (1)(B), making final determinations on claims for benefits under section 503A(b) (relating to internal appeals).

Where such an allocation is made, liability under a cause of action under paragraph (1) shall be assessed against the appropriate designated decision-maker.

"(D) QUALIFICATIONS.—

"(i) CERTIFICATION OF ABILITY.—To be appointed as a designated decision-maker under this paragraph, a person shall

provide to the plan sponsor or named fiduciary a certification of such person's ability to meet the requirements of clause (ii) relating to financial obligation for liability under this subsection. Such certification shall be provided upon appointment and not less frequently than annually thereafter, or if the designation is pursuant to a multi-year contract, in conjunction with the renewal of the contract, but in no case less than once every 3 years.

''(ii) OTHER REQUIREMENTS RELATING TO FINANCIAL OBLIGATIONS.—For purposes of clause (i), requirements relating to financial obligation for liability shall include evidence of—

''(I) coverage of the person under insurance policies or other arrangements, secured and maintained by the person, to insure the person against losses arising from professional liability claims, including those arising from being designated as a designated decision-maker under this paragraph; or

''(II) minimum capital and surplus levels that are maintained by the person to cover any losses as a result of liability arising from being designated as a designated decision-maker under this paragraph.

The appropriate amounts of liability insurance and minimum capital and surplus levels for purposes of subclauses (I) and (II) shall be determined by an actuary using sound actuarial principles and accounting practices pursuant to established guidelines of the American Academy of Actuaries and shall be maintained throughout the course of the contract in which such person is designated as a designated decision-maker.

''(E) FLEXIBILITY IN ADMINISTRATION.—A group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, may provide—

''(i) that any person or group of persons may serve in more than one capacity with respect to the plan or coverage (including service as a designated decision-

maker, administrator, and named fiduciary); or

"(ii) that a designated decision-maker may employ one or more persons to provide advice with respect to any responsibility of such decision-maker under the plan or coverage.

"(F) FAILURE TO APPOINT.—

"(i) IN GENERAL.—With respect to any cause of action under paragraph (1) relating to a denial of a claim for benefits where a designated decision-maker has not been appointed in accordance with this paragraph, the plan sponsor or named fiduciary responsible for determinations under section 503 shall be deemed to be the designated decision-maker.

"(ii) LIMITATION ON APPOINTMENT.—A treating health care professional who directly delivered the care, treatment, or provided the patient service that is the subject of an action under this subsection may not be designated as a designated decision-maker under this paragraph unless the professional—

"(I) is a person or entity that may be appointed in accordance with subparagraph (A); and

"(II) specifically agrees to accept such appointment in accordance with the requirements under such subparagraph.

"(3) REQUIREMENT OF EXHAUSTION OF INDEPENDENT MEDICAL REVIEW.—

"(A) IN GENERAL.—Paragraph (1) shall apply only if a final determination denying a claim for benefits under section 503A(b) has been referred for independent medical review under section 503B(d) and a written determination by an independent medical reviewer to reverse such final determination has been issued with respect to such review.

"(B) INJUNCTIVE RELIEF FOR IRREPARABLE HARM.—A participant or beneficiary may seek relief under subsection 502(a)(1)(B) prior to the exhaustion of administrative remedies under section 503A(b) or 503B (as required under subparagraph (A)) if it is demonstrated to the court, by a preponderance of the evidence, that the exhaustion of such rem-

edies would cause irreparable harm to the health of the participant or beneficiary. Any determinations that already have been made under section 503A or 503B in such case, or that are made in such case while an action under this subparagraph is pending, shall be given due consideration by the court in any action under this subsection in such case. Notwithstanding the awarding of relief under subsection 502(a)(1)(B) pursuant to this subparagraph, no relief shall be available under—

''(i) paragraph (1), with respect to a participant or beneficiary, unless the requirements of subparagraph (A) are met; or

''(ii) subsection (q) unless the requirements of such subsection are met.

''(4) LIMITATIONS ON RECOVERY OF DAMAGES.—

''(A) MAXIMUM AWARD OF NONECONOMIC DAMAGES.—The aggregate amount of liability for noneconomic loss in an action under paragraph (1) may not exceed $500,000.

''(B) INCREASE IN AMOUNT.—The amount referred to in subparagraph (A) shall be in-

creased or decreased, for each calendar year that ends after December 31, 2002, by the same percentage as the percentage by which the Consumer Price Index for All Urban Consumers (United States city average), published by the Bureau of Labor Statistics, for September of the preceding calendar year has increased or decreased from the such Index for September of 2002.

''(C) SEVERAL LIABILITY.—In the case of any action commenced pursuant to paragraph (1), the designated decision-maker shall be liable only for the amount of noneconomic damages attributable to such designated decision-maker in direct proportion to such decision-maker's share of fault or responsibility for the injury suffered by the participant or beneficiary. In all such cases, the liability of a designated decision-maker for noneconomic damages shall be several and not joint.

''(D) TREATMENT OF COLLATERAL SOURCE PAYMENTS.—

''(i) IN GENERAL.—In the case of any action commenced pursuant to paragraph (1), the total amount of damages received

by a participant or beneficiary under such action shall be reduced, in accordance with clause (ii), by any other payment that has been, or will be, made to such participant or beneficiary, pursuant to an order or judgment of another court, to compensate such participant or beneficiary for the injury that was the subject of such action.

''(ii) AMOUNT OF REDUCTION.—The amount by which an award of damages to a participant or beneficiary for an injury shall be reduced under clause (i) shall be—

''(I) the total amount of any payments (other than such award) that have been made or that will be made to such participant or beneficiary to pay costs of or compensate such participant or beneficiary for the injury that was the subject of the action; less

''(II) the amount paid by such participant or beneficiary (or by the spouse, parent, or legal guardian of such participant or beneficiary) to secure the payments described in subclause (I).

''(iii) DETERMINATION OF AMOUNTS FROM COLLATERAL SOURCES.—The reduction required under clause (ii) shall be determined by the court in a pretrial proceeding. At the subsequent trial no evidence shall be admitted as to the amount of any charge, payments, or damage for which a participant or beneficiary—

''(I) has received payment from a collateral source or the obligation for which has been assured by a third party; or

''(II) is, or with reasonable certainty, will be eligible to receive from a collateral source which will, with reasonable certainty, be assumed by a third party.

''(E) PROHIBITION OF AWARD OF PUNITIVE DAMAGES.—Notwithstanding any other provision of law, in the case of any action commenced pursuant to paragraph (1), the court may not award any punitive, exemplary, or similar damages against a defendant.

''(5) AFFIRMATIVE DEFENSES.—In the case of any cause of action under paragraph (1), it shall be an affirmative defense that—

''(A) the designated decision-maker of a group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, involved did not receive from the participant or beneficiary (or authorized representative) or the treating health care professional (if any), the information requested by the plan or issuer regarding the medical condition of the participant or beneficiary that was necessary to make a determination on a claim for benefits under section 503A(a) or a final determination on a claim for benefits under section 503A(b);

''(B) the participant or beneficiary (or authorized representative)—

''(i) was in possession of facts that were sufficient to enable the participant or beneficiary (or authorized representative) to know that an expedited review under section 503A or 503B would have prevented the harm that is the subject of the action; and

"(ii) failed to notify the plan or issuer of the need for such an expedited review; or

"(C) the qualified external review entity or an independent medical reviewer failed to meet the timelines applicable under section 503B, or a period of time elapsing after coverage has been authorized.

Nothing in this paragraph shall be construed to limit the application of any other affirmative defense that may be applicable to the cause of action involved.

"(6) WAIVER OF INTERNAL REVIEW.—In the case of any cause of action under paragraph (1), the waiver or nonwaiver of internal review under section 503A(b)(1)(D) by the group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, shall not be used in determining liability.

"(7) LIMITATIONS ON ACTIONS.—Paragraph (1) shall not apply in connection with any action that is commenced more than 3 years after the date on which the failure described in paragraph (1) occurred.

"(8) PROTECTION OF THE REGULATION OF QUALITY OF MEDICAL CARE UNDER STATE LAW.—

Nothing in this subsection shall be construed to preclude any action under State law against a person or entity for liability or vicarious liability with respect to the delivery of medical care. A claim that is based on or otherwise relates to a group health plan's administration or determination of a claim for benefits (as such term is defined in section 503B(i)(2) and notwithstanding the definition contained in paragraph (10)(B)) shall not be deemed to be the delivery of medical care under any State law for purposes of this section. Any such claim shall be maintained exclusively under section 502.

''(9) CONSTRUCTION.—Nothing in this subsection shall be construed as authorizing a cause of action under paragraph (1) for the failure of a group health plan or health insurance issuer to provide an item or service that is specifically excluded under the plan or coverage.

''(10) DEFINITIONS.—In this subsection:

''(A) AUTHORIZED REPRESENTATIVE.—The term 'authorized representative' has the meaning given such term in section 503B(i).

''(B) CLAIM FOR BENEFITS.—Except as provided for in paragraph (8), the term 'claim for benefits' shall have the meaning given such

term in section 503B(i), except that such term shall only include claims for prior authorization determinations (as such term is defined in section 503B(i)).

''(C) GROUP HEALTH PLAN.—The term 'group health plan' shall have the meaning given such term in section 733(a). In applying this paragraph, excepted benefits described in section 733(c) shall not be treated as benefits consisting of medical care.

''(D) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' has the meaning given such term in section 733(b)(1). In applying this paragraph, excepted benefits described in section 733(c) shall not be treated as benefits consisting of medical care.

''(E) HEALTH INSURANCE ISSUER.—The term 'health insurance issuer' has the meaning given such term in section 733(b)(2).

''(F) ORDINARY CARE.—The term 'ordinary care' means the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent individual acting in a like capacity and familiar with such matters would

use in making a determination on a claim for benefits of a similar character.

''(G) SUBSTANTIAL HARM.—The term 'substantial harm' means the loss of life, loss or significant impairment of limb or bodily function, significant mental illness or disease, significant disfigurement, or severe and chronic physical pain.

''(11) EFFECTIVE DATE.—The provisions of this subsection shall apply to acts and omissions occurring on or after the effective date of sections 503A and 503B (as contained in section 501 of the Bipartisan Patients' Bill of Rights Act of 2001).''.

(b) CONFORMING AMENDMENT.—Section 502(a)(1)(A) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(a)(1)(A)) is amended by inserting ''or (n)'' after ''subsection (c)''.

SEC. 142. LIMITATION ON CERTAIN CLASS ACTION LITIGATION.

(a) ERISA.—Section 502 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132), as amended by section 131, is further amended by adding at the end the following:

''(p) LIMITATION ON CLASS ACTION LITIGATION.—

''(1) IN GENERAL.—Any claim or cause of action that is maintained under this section in connection with a group health plan, or health insurance coverage issued in connection with a group health plan, as a class action, derivative action, or as an action on behalf of any group of 2 or more claimants, may be maintained only if the class, the derivative claimant, or the group of claimants is limited to the participants or beneficiaries of a group health plan established by only 1 plan sponsor. No action maintained by such class, such derivative claimant, or such group of claimants may be joined in the same proceeding with any action maintained by another class, derivative claimant, or group of claimants or consolidated for any purpose with any other proceeding. In this paragraph, the terms 'group health plan' and 'health insurance coverage' have the meanings given such terms in section 733.''.

''(2) EFFECTIVE DATE.—This subsection shall apply to all civil actions that are filed on or after the date of enactment of the Bipartisan Patients' Bill of Rights Act of 2001. This subsection shall apply to civil actions that are pending and have not been finally determined by judgment or settlement prior to such date of enactment.''.

(b) RICO.—Section 1964(c) of title 18, United States Code, is amended—

(1) by inserting ''(1)'' after the subsection designation; and

(2) by adding at the end the following:

''(2)(A) No action may be brought under this subsection, or alleging any violation of section 1962, where the action seeks relief concerning the manner in which any person has marketed, provided information concerning, established, administered, or otherwise operated a group health plan, or health insurance coverage in connection with a group health plan. Any such action shall only be brought under the Employee Retirement Income Security Act of 1974. In this paragraph, the terms 'group health plan' and 'health insurance issuer' shall have the meanings given such terms in section 733 of the Employee Retirement Income Security Act of 1974.

''(B) Subparagraph (A) shall apply to civil actions that are pending and have not been finally determined by judgment or settlement prior to the date of enactment of the Bipartisan Patients' Bill of Rights Act of 2001 and all actions commenced on or after such date.''.

SEC. 143. AUTHORITY TO IMPOSE CIVIL PENALTIES FOR FAILURE TO PROVIDE A PLAN BENEFIT NOT ELIGIBLE FOR MEDICAL REVIEW.

Section 502 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132), as amended by sections 131 and 141, is further amended by adding at the end the following:

''(q) In connection with any action maintained under subsection (a)(1)(B), the court, in its discretion, may assess a civil penalty against the designated decision-maker (as designated pursuant to section 502(n)(2)) of a group health plan or a health insurance issuer (that offers health insurance coverage in connection with a group health plan) of not to exceed $100,000 where—

''(1) in its final determination under section 503A(b)(4)(B), the designated decision-maker fails to provide, or authorize coverage of, a benefit to which a participant or beneficiary is entitled under the terms and conditions of the plan;

''(2) the participant or beneficiary has appealed such determination under section 503B and such determination is not subject to independent medical review as determined by a qualified external review entity under section 503B(c)(3)(A);

''(3) the plan has failed to exercise ordinary care in making a final determination under section

503A(b)(4)(B) denying a claim for benefits under the plan; and

''(4) that denial is the proximate cause of substantial harm (as defined in subsection (n)(10)(G)) the participant or beneficiary.''.

Subtitle E—State Flexibility

SEC. 151. PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.

(a) LIMITATION ON PREEMPTION OF STATE LAW WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

(1) IN GENERAL.—Subject to paragraph (2)—

(A) subtitles A and B of shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers (in connection with group health plans or individual health insurance coverage) and to non-Federal governmental plans except to the extent that such standard or requirement prevents the application of a requirement of such subtitles; and

(B) the amendments made by subtitle C shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or require-

ment solely relating to health insurance issuers in connection with individual health insurance coverage and to non-Federal governmental plans except to the extent that such standard or requirement prevents the application of a requirement of such amendments.

(2) CONTINUED PREEMPTION WITH RESPECT TO GROUP HEALTH PLANS.—Nothing in this title shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144) with respect to group health plans.

(b) CONTINUED APPLICATION OF CERTAIN STATE LAWS.—

(1) REQUIREMENTS FOR CONTINUED APPLICATION.—

(A) GENERAL RULE.—With respect to a State law described in subparagraph (B), in applying the requirements of subtitles A and B to health insurance issuers under sections 2707 and 2753 (as applicable) of the Public Health Service Act (as added by title II), or health insurance issuers in connection with group health plans under section 714 of the Employee Retirement Income Security Act of 1974 (as

added by title III), subject to subsection (a)(2)—

(i) the State law shall not be treated as being superseded under subsection (a); and

(ii) the State law shall apply in lieu of the patient protection requirements otherwise applicable under such subtitles with respect to health insurance issuers (in connection with group health plans or individual health insurance coverage) and non-Federal governmental plans.

(B) STATE LAW DESCRIBED.—A State law described in this subparagraph is a State law that imposes, with respect to health insurance issuers (in connection with group health plans or individual health insurance coverage) and to non-Federal governmental plans, a requirement that is approved by the Secretary (through a certification under subsection (c)(4)) as being consistent with a patient protection requirement (as defined in paragraph (3)).

(2) LIMITATION.—In the case of a group health plan covered under title I of the Employee Retirement Income Security Act of 1974, paragraph (1)

shall be construed to apply only with respect to the health insurance coverage (if any) offered in connection with the plan.

(3) PATIENT PROTECTION REQUIREMENT DEFINED.—For purposes of this section, the term ''patient protection requirement'' means any one or more requirements under the following:

(A) Section 101 (relating to access to emergency care).

(B) Section 102 (relating to consumer choice option) with respect to non-Federal governmental plans only.

(C) Section 103 (relating to patient access to obstetrical and gynecological care).

(D) Section 104 (relating to access to pediatric care).

(E) Section 105 (relating to timely access to specialists).

(F) Section 106 (relating to continuity of care), but only insofar as a replacement issuer assumes the obligation for continuity of care.

(G) Section 108 (relating to access to needed prescription drugs).

(H) Section 109 (relating to coverage for individuals participating in approved clinical trials).

(I) Section 110 (relating to required coverage for minimum hospital stay for mastectomies and lymph node dissections for the treatment of breast cancer and coverage for secondary consultations).

(J) A prohibition under—

(i) section 107 (relating to prohibition of interference with certain medical communications); and

(ii) section 111 (relating to prohibition of discrimination against providers based on licensure).

(K) An informational requirement under section 121.

(c) DETERMINATIONS WITH RESPECT TO CERTIFICATIONS.—

(1) IN GENERAL.—For purposes of the continued application of certain State laws under subsection (b)(1), a State may, on or after May 1, 2002, submit to the Board established under subsection (d) a certification that the State law involved is consistent with those patient protections require-

ments (as defined in subsection (b)(3)) that are covered under the law for which the State is seeking a certification. Such certification shall be accompanied by such information as may be required to permit the Board to make the determination described in paragraph (3), as applicable.

(2) ACTION BY BOARD.—

(A) IN GENERAL.—The Board shall promptly review a certification submitted under paragraph (1) with respect to a State law to make the determination required under paragraph (3) with respect to the certification.

(B) APPROVAL DEADLINES.—

(i) INITIAL REVIEW.—Not later than 60 days after the date on which the Board receives a certification under paragraph (1), the Board shall—

(I) notify the State involved that specified additional information is needed to make the determination described in paragraph (3); or

(II) submit a recommendation to the Secretary concerning the approval or disapproval (and the reasons therefore) of the certification.

(ii) ADDITIONAL INFORMATION.—With respect to a State that has been notified by the Board under clause (i)(I) that specified additional information is needed to make the determination described in paragraph (3), the Board shall make the submission required under clause (i)(II) within 60 days after the date on which such specified additional information is requested by the Board.

(3) DETERMINATION.—The Board shall recommend that the Secretary approve or disapprove a certification submitted under paragraph (1)(A). The Board shall recommend the approval of a certification under this subparagraph unless the Board finds that there is no reasonable basis or evidence for such approval.

(4) REVIEW BY SECRETARY.—

(A) IN GENERAL.—The recommendation by the Board to approve or disapprove a certification submitted by a State under paragraph (1) is considered to be approved by the Secretary unless the Secretary notifies the State in writing, within 30 days after the date on which the Board submits its recommendation to the

Secretary under paragraph (2) concerning such certification, that the certification is approved or disapproved (and the reasons for the approval or disapproval).

(B) DEFERENCE TO STATES.—The recommendation of the Board to approve a certification submitted under paragraph (1) shall be approved by the Secretary unless the Secretary finds that there is no reasonable basis or there is insufficient evidence for approving the certification.

(C) NOTICE.—

(i) STATE NOTIFICATION.—The Secretary shall provide a State with written notice of the determination of the Secretary to approve or disapprove the certification submitted by the State under paragraph (1) within 30 days after the date on which the Board submits its recommendation to the Secretary under paragraph (2) concerning such certification.

(ii) PUBLIC NOTIFICATION.—The Secretary shall publish each notice provided under clause (i) in the Federal Register and as otherwise determined appropriate

by the Secretary (including the Internet) to inform the general public. The Secretary shall annually publish (in accordance with the preceding sentence) the status of all States with respect to certifications.

(5) STATE CHALLENGE.—A State that has a certification disapproved by the Secretary under paragraph (4) may challenge such disapproval in the appropriate United States district court. The court shall make a de novo determination with respect to a challenge brought under this paragraph.

(6) TERMINATION OF CERTIFICATION.—

(A) IN GENERAL.—The Secretary, not more frequently than once every 5 years, may request that a State with respect to which a certification has been approved under paragraph (4), submit an assurance to the Secretary that with respect to a certification, the State law involved has not been—

(i) repealed; or

(ii) modified to such an extent that such law is no longer consistent with a patient protection requirement under this title.

(B) TERMINATION.—If a State fails to submit an assurance to the Secretary under subparagraph (A) within the 60-day period beginning on the date on which the Secretary makes a request for such an assurance, the certification applicable to the State under this section shall terminate.

(7) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a State from submitting more than one certification under paragraph (1).

(8) PETITIONS BY PLANS OR ISSUERS.—

(A) PETITION PROCESS.—Effective on the date on which the provisions of this Act become effective, as provided for in section 501, a group health plan or health insurance issuer may submit a petition to the Secretary for a determination as to whether or not a standard or requirement under a State law applicable to the plan or issuer, that is not the subject of a certification under subsection (c), is superseded under subsection (a)(1) because such standard or requirement prevents the application of a requirement of this title.

(B) APPROVAL.—The Secretary shall issue a determination with respect to a petition submitted under subparagraph (A) within the 60-day period beginning on the date on which such petition is submitted.

(d) PATIENTS' PROTECTION BOARD.—

(1) ESTABLISHMENT OF BOARD.—

(A) IN GENERAL.—There is hereby established in the Department of Health and Human Services a Patients' Protection Board. Consistent with the requirements of sections 5 and 10 of the Federal Advisory Committee Act, the Board shall carry out the duties described in paragraph (2).

(B) COMPOSITION.—The Board shall be composed of 13 members appointed by the Secretary with balanced representation from among individuals who represent consumers, employers, health professionals, health insurance issuers, and officials of State government. Members shall first be appointed to the Board not later than May 1, 2002.

(C) TERMS.—The terms of the members of the Board shall be for 3 years except that for the members first appointed the Secretary shall

designate staggered terms of 3 years for 2 members, 2 years for 2 members, and 1 year for 1 member. A vacancy on the Board shall be filled in the same manner in which the original appointment was made and a member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term.

(2) DUTIES.—

(A) REVIEW OF CERTIFICATIONS SUBMITTED.—The Board shall review certifications submitted under subsection (c) and make recommendations to the Secretary of Health and Human Services as provided for in such subsection.

(B) ANNUAL CONGRESSIONAL REPORTS.—

(i) IN GENERAL.—The Board shall submit to Congress an annual report on its activities. Each such report shall include the findings of the Board as to—

(I) the States that have failed to obtain a certification under subsection (c); and

(II) whether the enforcement role of the Federal Government with respect to health insurance has substantially expanded.

(ii) INITIAL REPORT.—The first annual report under clause (i) shall focus specifically on the development by the Board of criteria for the evaluation of State laws and any other activities of the Board during its first year of operation.

(e) DEFINITIONS.—For purposes of this section:

(1) BOARD.—The term ''Board'' means the Patients' Protection Board established under subsection (d).

(2) STATE, STATE LAW.—The terms ''State'' and ''State law'' shall have the meanings given such terms in section 2723(d) of the Public Health Service Act (42 U.S.C. 300gg–23(d)).

Subtitle F—Miscellaneous Provisions

SEC. 161. DEFINITIONS.

(a) INCORPORATION OF GENERAL DEFINITIONS.—Except as otherwise provided, the provisions of section 2791 of the Public Health Service Act shall apply for pur-

poses of this title in the same manner as they apply for purposes of title XXVII of such Act.

(b) SECRETARY.—Except as otherwise provided, the term ''Secretary'' means the Secretary of Health and Human Services, in consultation with the Secretary of Labor.

(c) ADDITIONAL DEFINITIONS.—For purposes of this title:

(1) ENROLLEE.—The term ''enrollee'' means, with respect to health insurance coverage offered by a health insurance issuer, an individual enrolled with the issuer to receive such coverage.

(2) HEALTH CARE PROFESSIONAL.—The term ''health care professional'' means an individual who is licensed, accredited, or certified under State law to provide specified health care services and who is operating within the scope of such licensure, accreditation, or certification.

(3) HEALTH CARE PROVIDER.—The term ''health care provider'' includes a physician or other health care professional, as well as an institutional or other facility or agency that provides health care services and that is licensed, accredited, or certified to provide health care items and services under applicable State law.

(4) NETWORK.—The term ''network'' means, with respect to a group health plan or health insurance issuer offering health insurance coverage, the participating health care professionals and providers through whom the plan or issuer provides health care items and services to participants, beneficiaries, or enrollees.

(5) NONPARTICIPATING.—The term ''nonparticipating'' means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health insurance coverage, a health care provider that is not a participating health care provider with respect to such items and services.

(6) PARTICIPATING.—The term ''participating'' means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health insurance coverage offered by a health insurance issuer, a health care provider that furnishes such items and services under a contract or other arrangement with the plan or issuer.

(7) PRIOR AUTHORIZATION.—The term ''prior authorization'' means the process of obtaining prior approval from a health insurance issuer or group

health plan for the provision or coverage of medical services.

(8) TERMS AND CONDITIONS.—The term ''terms and conditions'' includes, with respect to a group health plan or health insurance coverage, requirements imposed under this title with respect to the plan or coverage.

TITLE II—AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT

SEC. 201. APPLICATION TO CERTAIN HEALTH INSURANCE COVERAGE.

(a) IN GENERAL.—Subpart 2 of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–4 et seq.) is amended by adding at the end the following:

''SEC. 2707. PATIENT PROTECTION STANDARDS AND ACCOUNTABILITY.

''(a) IN GENERAL.—Each health insurance issuer shall comply with the patient protection requirements under title I of the Bipartisan Patients' Bill of Rights Act of 2001 with respect to non-Federal governmental group health insurance coverage offered by such issuers, and such requirements shall be deemed to be incorporated into this section.

''(b) ACCOUNTABILITY.—The provisions of sections 503 through 503B of the Employee Retirement Income Security Act of 1974 (as in effect as of the day after the date of enactment of the Bipartisan Patients' Bill of Rights Act of 2001) shall apply to non-Federal governmental group health insurance coverage offered by health insurance issuers with respect to an enrollee in the same manner as they apply to health insurance coverage offered by a health insurance issuer for a participant or beneficiary in connection with a group health plan and the requirements referred to in such sections shall be deemed to be incorporated into this section. For purposes of this subsection, references in such sections 503 through 503B to the Secretary shall be deemed to be references to the Secretary of Health and Human Services.''.

(b) CONFORMING AMENDMENT.—Section 2721(b)(2)(A) of such Act (42 U.S.C. 300gg–21(b)(2)(A)) is amended by inserting ''(other than section 2707)'' after ''requirements of such subparts''.

SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSURANCE COVERAGE.

Part B of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–41 et seq.) is amended—

(1) by redesignating the first subpart 3 (relating to other requirements) as subpart 2; and

(2) by inserting after section 2752 the following:

"SEC. 2753. PATIENT PROTECTION STANDARDS AND ACCOUNTABILITY.

''(a) IN GENERAL.—Each health insurance issuer shall comply with the patient protection requirements under subtitles A and B of title I of the Bipartisan Patients' Bill of Rights Act of 2001 with respect to individual health insurance coverage it offers, and such requirements shall be deemed to be incorporated into this section.''.

''(b) ACCOUNTABILITY.—The provisions of sections 503 through 503B of the Employee Retirement Income Security Act of 1974 (as in effect as of the day after the date of enactment of the Bipartisan Patients' Bill of Rights Act of 2001) shall apply to health insurance coverage offered by a health insurance issuer in the individual market with respect to an enrollee in the same manner as they apply to health insurance coverage offered by a health insurance issuer for a participant or beneficiary in connection with a group health plan and the requirements referred to in such sections shall be deemed to be incorporated into this section. For purposes of this subsection, references in such sections 503 through 503B to the Secretary shall be deemed to be references to the Secretary of Health and Human Services.''.

SEC. 203. LIMITATION ON AUTHORITY OF THE SECRETARY OF HEALTH AND HUMAN SERVICES WITH RESPECT TO NON-FEDERAL GOVERNMENTAL PLANS.

Section 2722(b) of the Public Health Service Act (42 U.S.C. 300gg–22(b)) is amended—

(1) in paragraph (1), by striking ''only—'' and all that follows through the period and inserting ''only as provided under subsection (a)(2).''; and

(2) in paragraph (2)—

(A) in subparagraph (A), by striking ''any non-Federal governmental plan that is a group health plan and''; and

(B) in subparagraph (B), by striking ''by—'' and all that follows through the period and inserting ''by a health insurance issuer, the issuer is liable for such penalty.''.

SEC. 204. COOPERATION BETWEEN FEDERAL AND STATE AUTHORITIES.

Part C of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–91 et seq.) is amended by adding at the end the following:

''SEC. 2793. COOPERATION BETWEEN FEDERAL AND STATE AUTHORITIES.

''(a) AGREEMENT WITH STATES.—A State may enter into an agreement with the Secretary for the delegation

to the State of some or all of the Secretary's authority under this title to enforce the requirements applicable under title I of the Bipartisan Patients's Bill of Rights Act of 2001 to health insurance issuers in connection with non-Federal governmental plans and individual health insurance coverage.

''(b) DELEGATIONS.—Any department, agency, or instrumentality of a State to which authority is delegated pursuant to an agreement entered into under this section may, if authorized under State law and to the extent consistent with such agreement, exercise the powers of the Secretary under this title which relate to such authority.''.

TITLE III—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

SEC. 301. APPLICATION OF PATIENT PROTECTION STANDARDS TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.) is further amended by adding at the end the following new section:

"SEC. 714. PATIENT PROTECTION STANDARDS.

"(a) IN GENERAL.—Subject to subsection (b), a group health plan (and a health insurance issuer offering health insurance coverage in connection with a group health plan) shall comply with the requirements of title I of the Bipartisan Patients' Bill of Rights Act of 2001 (as in effect as of the date of the enactment of such Act), and such requirements shall be deemed to be incorporated into this subsection.

"(b) PLAN SATISFACTION OF CERTAIN REQUIREMENTS.—

"(1) SATISFACTION OF CERTAIN REQUIREMENTS THROUGH INSURANCE.—For purposes of subsection (a), insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the following requirements of title I of the Bipartisan Patients' Bill of Rights Act of 2001 with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer:

"(A) Section 101 (relating to access to emergency care).

"(B) Section 102 (relating to consumer choice option).

"(C) Section 103 (relating to patient access to obstetrical and gynecological care).

"(D) Section 104 (relating to access to pediatric care).

"(E) Section 105 (relating to timely access to specialists).

"(F) Section 106 (relating to continuity of care), but only insofar as a replacement issuer assumes the obligation for continuity of care.

"(G) Section 108 (relating to access to needed prescription drugs).

"(H) Section 109 (relating to coverage for individuals participating in approved clinical trials).

"(I) Section 110 (relating to required coverage for minimum hospital stay for mastectomies and lymph node dissections for the treatment of breast cancer and coverage for secondary consultations).

"(J) Section 121 (relating to the provision of information).

"(2) APPLICATION TO PROHIBITIONS.—Pursuant to rules of the Secretary, if a health insurance

issuer offering health insurance coverage in connection with a group health plan takes an action in violation of any of the following sections of the Bipartisan Patients' Bill of Rights Act of 2001, the group health plan shall not be liable for such violation unless the plan caused such violation:

"(A) Section 107 (relating to prohibition of interference with certain medical communications).

"(B) Section 111 (relating to prohibition of discrimination against providers based on licensure).

"(3) CONSTRUCTION.—Nothing in this subsection shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B.

"(4) TREATMENT OF CONSISTENT STATE LAWS.—For purposes of applying this subsection, a health insurance issuer offering coverage in connection with a group health plan (and such group health plan) shall be deemed to be in compliance with one or more of the patient protection requirements of the Bipartisan Patients' Bill of Rights Act of 2001 (as defined in section 151(b)(3) of such

Act) that are otherwise applicable to such issuer (or plan) under this section where—

"(A) the issuer (or plan) is in compliance with a State law, with respect to the patient protection requirements involved, that has been certified in accordance with section 151(c) of such Act; or

"(B) the issuer (or plan) is in compliance with a State law, with respect to the patient protection requirements involved, that has been determined by the Secretary as not preventing the application of the patient protection requirements involved, in accordance with section 151(c)(8)(B) of such Act.

"(c) CONFORMING REGULATIONS.—The Secretary shall issue regulations to coordinate the requirements on group health plans and health insurance issuers under this section with the requirements imposed under the other provisions of this title.".

(b) SATISFACTION OF ERISA CLAIMS PROCEDURE REQUIREMENT.—Section 503 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1133) is amended—

(1) by inserting "(a)" after "SEC. 503."; and

(2) by adding at the end the following:

''(b) In the case of a group health plan (as defined in section 733) compliance with the requirements of subtitle A of title I of the Bipartisan Patients' Bill of Rights Act of 2001, and compliance with regulations promulgated by the Secretary, in the case of a claims denial shall be deemed compliance with subsection (a) with respect to such claims denial.''.

(c) ENFORCEMENT.—Section 502(b)(3) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(b)(3)) is amended—

(1) by striking ''The Secretary'' and inserting ''(A) The Secretary''; and

(2) by adding at the end the following:

''(B) A participant, beneficiary, plan fiduciary, or the Secretary may not bring an action to enforce the requirements of section 714 against a health insurance issuer offering coverage in connection with a group health plan (or such group health plan) where the patient protection requirements of the Bipartisan Patients' Bill of Rights Act of 2001 (as defined in section 151(b)(3) of such Act) otherwise applicable to such issuer (or plan) under section 714 do not apply because the issuer (or plan) is in compliance with a State law, with respect to the patient protection requirements involved, that has been certified or a

determination made in accordance with section 151 of such Act.''.

(d) CONFORMING AMENDMENTS.—

(1) Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185(a)) is amended by striking ''section 711'' and inserting ''sections 711 and 714''.

(2) The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by inserting after the item relating to section 713 the following new item:

''Sec. 714. Patient protection standards.''.

(3) Section 502(b)(3) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(b)(3)) is amended by inserting ''(other than section 135(b))'' after ''part 7''.

SEC. 302. COOPERATION BETWEEN FEDERAL AND STATE AUTHORITIES.

Section 506 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1136) is amended by adding at the end the following:

''(c) RESPONSIBILITY OF STATE WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

''(1) AGREEMENT WITH STATES.—A State may enter into an agreement with the Secretary for the delegation to the State of some or all of the Sec-

retary's authority under sections 502, 503A, 503B, or 504 to enforce the requirements applicable under title I of the Bipartisan Patients's Bill of Rights Act of 2001 to health insurance issuers in connection with a group health plan.

''(2) DELEGATIONS.—Any department, agency, or instrumentality of a State to which authority is delegated pursuant to an agreement entered into under this subsection may, if authorized under State law and to the extent consistent with such agreement, exercise the powers of the Secretary under this title which relate to such authority.''.

TITLE IV—AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986

SEC. 401. APPLICATION TO GROUP HEALTH PLANS UNDER THE INTERNAL REVENUE CODE OF 1986.

Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended—

(1) in the table of sections, by inserting after the item relating to section 9812 the following new item:

''Sec. 9813. Standard relating to patients' bill of rights.'';

and

(2) by inserting after section 9812 the following:

"SEC. 9813. STANDARD RELATING TO PATIENTS' BILL OF RIGHTS.

"A group health plan shall comply with the requirements of title I of the Bipartisan Patients' Bill of Rights Act of 2001 (as in effect as of the date of the enactment of such Act), and such requirements shall be deemed to be incorporated into this section.".

SEC. 402. CONFORMING ENFORCEMENT FOR WOMEN'S HEALTH AND CANCER RIGHTS.

Subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by section 401, is further amended—

(1) in the table of sections, by inserting after the item relating to section 9813 the following new item:

"Sec. 9814. Standard relating to women's health and cancer rights.";

and

(2) by inserting after section 9813 the following:

"SEC. 9814. STANDARD RELATING TO WOMEN'S HEALTH AND CANCER RIGHTS.

"The provisions of section 713 of the Employee Retirement Income Security Act of 1974 (as in effect as of the date of the enactment of this section) shall apply to group health plans as if included in this subchapter.".

TITLE V—EFFECTIVE DATE; SEVERABILITY

SEC. 501. EFFECTIVE DATE AND RELATED RULES.

Except as otherwise provided in this Act, the provisions of this Act, including the amendments made by title I, shall apply on the later of—

(1) plan years beginning on or after January 1, 2003; or

(2) plan years beginning on or after 18 months after the date on which the Secretary of Health and Human Services and the Secretary of Labor issue final regulations, subject to the notice and comment period required under subchapter 2 of chapter 5 of title 5, United States Code, necessary to carry out the amendments made by this Act.

SEC. 502. SEVERABILITY.

(a) IN GENERAL.—Except as provided in subsections (b) and (c), if any provision of this Act, an amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such to any person or circumstance shall not be affected thereby.

(b) DEPENDENCE OF REMEDIES ON APPEALS.—If any provision of section 131, or the amendments made by such section, or the application of such section or amendments to any person or circumstance is held to be unconstitutional, sections 141 and 143, and the amendments made by such sections, shall be deemed to be null and void and shall be given no force or effect.

(c) REMEDIES.—If any provision of section 141, or the amendments made by such section, or the application of such section or amendments to any person or circumstance is held to be unconstitutional, the remainder of such section, and the amendments made by such section shall be deemed to be null and void and shall be given no force or effect.

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